UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ACTELION PHARMACEUTICALS LTD. and ACTELION CLINICAL RESEARCH, INC., **CIVIL ACTION NUMBER:**

Plaintiffs, **12-cv-05743-NLH**

-vs- **MOTIONS HEARING**

APOTEX, INC., APOTEX CORP., ROXANE LABORATORIES, INC., and ACTAVIS ELIZABETH LLC,

Defendants and Counterclaim Plaintiffs.

Mitchell H. Cohen United States Courthouse
One John F. Gerry Plaza
Camden, New Jersey 08101
October 17, 2013

B E F O R E: **THE HONORABLE NOEL L. HILLMAN**
UNITED STATES DISTRICT JUDGE

A P P E A R A N C E S:

DECHERT LLP
BY: GEORGE G. GORDON, ESQUIRE
BY: CAROLYN E. BUDZINSKI, ESQUIRE
BY: EZRA D. ROSENBERG, ESQUIRE
ATTORNEYS FOR PLAINTIFFS

KIRKLAND & ELLIS LLP
BY: KAREN N. WALKER, ESQUIRE
BY: ANDREW C. PHILLIPS, ESQUIRE
ATTORNEYS FOR DEFENDANT/COUNTERCLAIM PLAINTIFF, ROXANE LABORATORIES, INC.

SILLS CUMMIS & GROSS
BY: DAVID L. COOK, ESQUIRE
ATTORNEYS FOR DEFENDANT/COUNTERCLAIM PLAINTIFF, ROXANE LABORATORIES

A P P E A R A N C E S (Cont.)

ZUCKERMAN SPAEDER LLP
BY: AITAN D. GOELMAN, ESQUIRE
BY: ALEXANDRA W. MILLER, ESQUIRE
ATTORNEYS FOR DEFENDANT/COUNTERCLAIM PLAINTIFF
APOTEX, INC.

LATHAM & WATKINS LP
BY: AMANDA P. REEVES, ESQUIRE
ATTORNEYS FOR DEFENDANT/COUNTERCLAIM PLAINTIFF,
ACTAVIS ELIZABETH

SKADDEN, ARPS, SLATE, MEAGHER & FLOM LLP
BY: ANDREW MUSCATO, ESQUIRE
BY: JULIA K. YORK, ESQUIRE
ATTORNEYS FOR DEFENDANT/COUNTERCLAIM PLAINTIFF,
JOHNSON MATTHEY, INC.

THE LAW OFFICE OF JASON B. LATTIMORE, ESQUIRE, LLC
BY: JASON B. LATTIMORE, ESQUIRE
ATTORNEYS FOR DEFENDANT/COUNTERCLAIM PLAINTIFF,
ACTAVIS ELIZABETH, LLC

HILL WALLACK LLP
BY: ERIC I. ABRAHAM, ESQUIRE
ATTORNEYS FOR ZYDUS PHARMACEUTICALS

LOCKE LORD LLP
BY: RANDALL A. HACK, ESQUIRE
ATTORNEYS FOR ZYDUS PHARMACEUTICALS

BAZELON LESS & FELDMAN, P.C.
BY: MICHAEL A. SHAPIRO, ESQUIRE
ATTORNEYS FOR DEFENDANTS/COUNTERCLAIM PLAINTIFFS,
APOTEX

Certified as true and correct as required by Title 28, U.S.C., Section 753.

/S/ Carol A. Farrell, CCR, CRR, RMR, CCP

(OPEN COURT on October 17, 2013, at 1:45 p.m.)

THE DEPUTY CLERK: All rise.

THE COURT: All right. Good afternoon. Uh-oh, we have the screen down. Please be seated except for counsel.

Let me have appearances. This is -- well, Actelion?

MR. GORDON: Yes, Your Honor.

THE COURT: Actelion, all right. An easier name was unavailable, I guess. Exxon was -- Merck was already taken.

MR. GORDON: We can change it if you prefer, Your Honor.

THE COURT: That's okay. I just wanted to get it right. And I apologize pausing.

Who do we have for the plaintiff?

MR. GORDON: George Gordon from Dechert LLP for the plaintiffs.

THE COURT: All right, Mr. Gordon, welcome.

MR. GORDON: Thank you, Your Honor.

MS. BUDZINSKI: Carolyn Budzinski from Dechert for the plaintiffs.

MR. ROSENBERG: And Ezra Rosenberg also from Dechert for the plaintiffs.

THE COURT: All right. Welcome to you as well. You may be seated after you make your appearance.

Who else do we have here? This is for defendants.

MS. WALKER: For the defendants and counterclaim

plaintiffs, Your Honor, Karen Walker from Kirkland & Ellis for Roxane Labs, Inc.

THE COURT: All right. Welcome.

MR. GOELMAN: Good afternoon, Your Honor. For defendant and counterclaim plaintiff Apotex, Incorporated, Aitan Goelman, Zuckerman Spaeder.

THE COURT: All right. Welcome, sir.

MR. GOELMAN: Thank you.

THE COURT: Wait a second. Let me find you on here. Mr. Goelman, did you say?

MR. GOELMAN: Yes, Your Honor.

THE COURT: All right. I'm sure you're on here. Who's your client?

MR. GOELMAN: Apotex, Inc.

THE COURT: All right. Well, welcome, sir.

MR. GOELMAN: Thank you.

THE COURT: All right. Who else do we have?

MS. REEVES: Good afternoon, Your Honor. Amanda Reeves of Latham & Watkins on behalf of Actavis Elizabeth.

THE COURT: All right, Ms. Reeves, welcome. Feel free to be seated when you tell me who you are. Sorry.

All right. Who do we have back there?

MR. PHILLIPS: Andrew Phillips from Kirkland & Ellis for Roxane Labs, Your Honor.

THE COURT: All right, Mr. Phillips, welcome.

MS. MILLER: Alexandra Miller from Zuckerman Spaeder on behalf of Apotex, Your Honor.

THE COURT: All right, Ms. Miller, welcome to you as well. Did you arrange yourselves on who is going to speak? I will ask that next.

Who else do we have?

MR. MUSCATO: Your Honor, good afternoon. Andrew Muscato from Skadden, Arps, Slate, Meagher, Flom for defendant/counterclaimant, Johnson Matthey, Inc.

THE COURT: All right, Mr. Muscato.

MR. MUSCATO: I also have Julia York from our Washington office who is here.

THE COURT: All right. Welcome. I guess that was a housekeeping issue that I need to take up with you, but welcome to you both. Johnson Matthey, do they have a business other than pharmaceuticals?

MS. YORK: Yes, Your Honor.

THE COURT: Metals?

MS. YORK: Yes, I believe that's correct.

THE COURT: Oh, okay. All right. Has it always been in the pharmaceutical business?

MS. YORK: It's the manufacturer of the pharmaceutical ABI, an active pharmaceutical ingredient.

THE COURT: Oh, I see. All right. Maybe there's more metal in pharmaceuticals than I realized.

(Laughter.)

THE COURT: Free enterprise, so they're free to go into any market they want. That's not an attempt to telegraph an answer here.

(Laughter.)

THE COURT: All right. Who else do we have?

MR. LATTIMORE: Good afternoon, Your Honor. Jason Lattimore of the Lattimore Law Office on behalf of defendant/counterclaimant Actavis Elizabeth, LLC.

THE COURT: All right, Mr. Lattimore, welcome to you as well.

Go ahead.

MR. ABRAHAM: Good afternoon, Judge. From Hill Wallack in Princeton, New Jersey, Eric Abraham on behalf of Zydus.

THE COURT: All right, Mr. Abraham, welcome.

MR. HACK: Your Honor, good afternoon. From Locke Lord in Chicago, Randy Hack for Zydus Pharmaceuticals.

THE COURT: All right. Welcome to you as well, sir.

MR. HACK: Thank you, sir.

THE COURT: Your last name again? Hack? Mr. Hack?

MR. HACK: Your Honor, H-A-C-K, Hack. Thank you.

THE COURT: Yes. Welcome, sir.

MR. COOK: I'm David Cook, from Sills, Cummis & Gross, for Roxane Laboratories as well, Your Honor.

THE COURT: All right. Welcome.

MR. SHAPIRO: Good afternoon.

THE COURT: Did we find you a seat in the well of the court? We did not. That's bad. There's seats up here.

MR. SHAPIRO: Bazeon, Less & Feldman for Apotex, defendants.

THE COURT: All right, Mr. Feldman. Did I get that right?

MR. SHAPIRO: Michael Shapiro.

THE COURT: Oh, Shapiro. Mr. Shapiro, I'm sorry. Oh, Feldman is in the firm. All right, Mr. Shapiro, welcome.

All right. We have appearances by everyone. All right. Where do we start? My word.

I suppose I should start by offering my gratitude to the parties for their helpful briefs. This matter is complicated, involves some substantial issues. Some of the briefing suggests the weight of the world may turn on this decision, but I have to say, the briefs were very good and very helpful and I appreciate that.

And this always presents a dilemma for me because the more helpful the briefs are, perhaps, at times, the less utility derived from oral argument; and the corollary to that is the worse the briefs are, the less helpful oral argument tends to be.

(Laughter.)

THE COURT: So I'm happy to hear anything you want to add, but I don't know that there's anything left unsaid. But I guess I do have some questions.

So housekeeping. There were -- does it remain unresolved -- do we have -- the FDC and the Manufacturers' Association, are they here? Do they wish to be heard? Or are they going to rely on the arguments raised by the defendants in this case?

MS. WALKER: We have been in contact with the FDC, Your Honor. Obviously, their situation is a little bit strained in light of the government shutdown. The attorneys that were involved in this matter who did the amicus brief were shut down.

THE COURT: They can't walk from DC?

MS. WALKER: They were shut down and they would have liked to participate but had told us, in light of the shutdown, that they wouldn't. As we all have heard overnight, there seems to have been a resolution, but they were not able to -- to turn around and participate on such short notice for them. So we will proceed without them, although we obviously have their brief and can comment on that.

THE COURT: All right. Did I read the docket right? Their motion -- it's unopposed but ungranted, to file an amicus. Is that the current status? Do we know? I suppose that should be for me to decide.

Is there any opposition to their --

MR. GORDON: No, Your Honor, no opposition.

THE COURT: All right. I'm going to grant the application. Their brief was helpful as well. And I should say the same for the -- I will get the name wrong. How about the trade association for the generic industry? Ms. Walker, do you have insight on that as well?

MS. WALKER: Yes, obviously --

THE COURT: They are not restricted by funding, I imagine.

MS. WALKER: I don't think so. But they have --

THE COURT: But they would have to come from Washington probably.

MS. WALKER: They have a small staff and are not present either.

I believe most, if not all, of the counterclaim plaintiffs are members of the association, so we can certainly speak to any questions that their submission might raise.

THE COURT: All right. Mr. Gordon, do you have any objection to their brief being considered by the Court?

MR. GORDON: No, Your Honor.

THE COURT: All right. Then we'll grant that motion as well. I did read them and will consider them, although I think -- some of it was helpful, some of it's duplicative. But, in any event.

All right. And was there a motion regarding Johnson Matthey that I needed to rule on? There -- it came in here --

MR. MUSCATO: I believe, Your Honor, our motion as to leave was granted awhile ago and the --

THE COURT: All right.

MR. MUSCATO: Motion --

THE COURT REPORTER: I'm sorry, sir. I can't hear you and I need your name.

MR. MUSCATO: Andrew Muscato.

THE COURT REPORTER: And I didn't hear what you said.

MR. MUSCATO: I said, Your Honor, I believe whatever motions that have been made on our behalf have been granted by the Court.

THE COURT: Thank you for repeating that, Mr. Muscato, and I should have recognized that on the docket.

And I won't snatch defeat from the jaws of victory. You remain as an intervenor, so welcome to the case.

All right. The -- I guess I will -- I will start with Mr. Gordon.

Isn't the narrow issue before me now -- and in your reply brief, you do a good job of laying out a list of the facts that you believe are pled in the counterclaim -- that you would say, if accepted as -- even if accepted as true, do not state a claim, isn't the narrow question before me whether the matter should proceed to discovery so that Roxane and

Apotex and the other companies involved here may develop facts to supplement or prove a plausible claim that this case involves something beyond a mere refusal to deal? And wouldn't I be safer, sitting here now, to have the full kind of factual development that the Court of Appeals -- rather, the Supreme Court in Aspen Highlands had in determining whether or not this -- this -- the allegations here bear out a claim under Section 2?

I would add to that that Trinko, although it apparently was a dismissal early on, it had the benefit of a rather extensive administrative record at the regulatory level. I guess all of that is a longwinded way of saying I'm not entirely comfortable with the notion that, on the limited facts available to me, that you always have a right under all circumstances to refuse to sell samples to generic companies. Where does that -- from where do you derive that broad, all-encompassing, seemingly invincible principle?

MR. GORDON: Well, Your Honor, I think you framed -- I think you have framed the issue correctly. I think the issue before the Court is whether or not, based on the facts pled, there's been enough pled to justify this case proceeding to discovery.

And, if I may, because I may refer to some of our slides, although probably not all of them. If I may approach the bench with hard copy of our slides, Your Honor?

THE COURT: Sure. And my only hesitancy is I feel guilty for not inviting the FDC to call in, but -- since we have the screen, but I don't like to do that anyway. But I appreciate this. Thank you.

MR. GORDON: So, Your Honor, in terms of the source of Actelion's right, and I would not suggest that there is a right here -- let me step back. I would not suggest that there is an unqualified right in all circumstances always and in all instances not to deal with a rival. I think the Supreme Court has made clear that that right can be qualified, but only in certain very narrow circumstances.

I mean, if you look at the Aspen Skiing case itself, Your Honor, that was a fairly egregious set of facts. You had a situation where there were -- there was a course of dealing that had developed before Ski Company, the defendant, allegedly even had monopoly power. I think at the time it only came to maybe one, maybe two of the mountains in Aspen, and it had gone on for well over a decade before Ski Company obtained monopoly power and then abruptly pulled the rug out from under Aspen Highlands. It not only -- not only did, in Aspen Skiing, the alleged monopolist stop the All Aspen Ski Pass, which I would be a big proponent of myself, Your Honor.

THE COURT: Me too. We all like that.

MR. GORDON: Not only did it pull the All Aspen Ski Pass, it wouldn't even sell its own tickets, lift tickets, to

Aspen Highlands to provide to its skiers, so Aspen Highlands could kind of cobble together its own effective pass, all after, I think for 14 or 15 years --

THE COURT: Or honor the coupons.

MR. GORDON: Or honor the coupons.

THE COURT: In the subsequent plan to get around the exclusion.

MR. GORDON: Exactly.

So when you look at Aspen, when you look at Aspen Skiing, I think what you have is -- what the Court has defined is a fairly egregious set of circumstances that will justify potentially antitrust liability based on a refusal to deal.

And Trinko, the Court in Trinko itself, when it was looking at the refusal to deal doctrine, and asking the very question, you know, well, under what circumstances can it be qualified, the only circumstances it identified was the situation in Aspen Skiing where there had been a long-term profitable voluntary course of dealing in play, and, indeed, identified that as being a situation itself which was at or near the boundaries of Section 2 liability.

If I may --

THE COURT: Isn't -- I don't want to jump ahead here, but since you've framed the issue this way, and I think it's helpful, isn't a key difference between Trinko and Aspen Highlands the pricing or profit -- or the conduct designed to

control pricing or -- or to control profits? In Aspen, it seemed to me that one of the key aspects of the Court's decision was the refusal to sell at retail, coupled with this attempt to extract an agreement to accept a lower proportion of the joint profits, inconsistent with the historical profits earned by the Lone Mountain. In other words, although it was trending down, it was 20, 18, 17, in the last year or so, it was 13 or 14 percent, and they said, well, we'll let you continue in this four-mountain pass, but only if you accept 12 percent of the profits, even if -- and in the absence of any kind of real monitoring. In other words, we're going to take two or three percent more out of you in order to participate, and that long-term potential profit was more beneficial to them than the short-term profit of the retail sales that they were foregoing as a result of the Lone Mountain's efforts to create a separate pass.

In Trinko, in Verizon, none of the -- the plaintiff was -- which happened to be a law firm filing on the day after a consent decree which I think had a lot --

(Laughter.)

THE COURT: Which I think had a lot to do with the Court's decision as well. Maybe. I don't know. I can't --

MR. GORDON: Not a particularly attractive plaintiff, Your Honor.

THE COURT: But Verizon wasn't -- but Verizon's

rate -- Verizon's conduct in slowly processing orders didn't seem to be driven by a profit motive or an extension of their monopoly or to extract monopolistic profits. In fact, the rate that they were charging for processing the orders had been mandated by the regulatory scheme.

Isn't this case, at least the allegations of the defendants, as it relates to extending a monopoly or extracting monopolistic profits, more like Aspen Highlands than it is like Trinko?

MR. GORDON: I don't think so, Your Honor, for a few different reasons.

Number one, what's entirely missing from this case, which was critical in Aspen Highlands, noted by Trinko and has been noted by courts in the 2nd, 9th, 10th and 11th Circuit as being a requirement for a refusal to deal case is that long term.

THE COURT: Prior course --

MR. GORDON: I mean -- this was Aspen Skiing's business model for many years. And I think you accurately described the offer it had made, and in fact, I think one of its witnesses described it as an offer that they couldn't accept --

THE COURT: Right.

MR. GORDON: -- or they had to refuse or words to that effect.

THE COURT: Right.

MR. GORDON: So that's a significant difference.

Here, Actelion is not in the business of selling samples. I mean, we're talking about something that is very different than Actelion's business model. Actelion has never sold or done business in any way with any of these defendants. Doesn't want to do business with the defendants now, doesn't want to do business with the defendants in the future.

And that's a critical distinction. And courts have recognized, and if you looked at the Christy's decision from the Tenth Circuit, the Court was very clear there that, you know, the Sherman Act, absent a prior profitable course of dealing, the Sherman Act doesn't require even monopolists to assist a competitor in coming in and stealing away its own customer base.

And there's an additional issue here, Your Honor, with respect to the countervailing issues that are in play with the providing of these samples. These are drugs, Zavesca and Tracleer, that are -- they're efficacious. They're effective drugs, but they have serious side effects. Tracleer has a black box warning which is the highest level of warning that the FDA can give for a drug. So there are serious risks with administering these drugs to human patients.

And part of what is at play here, which was at play in Trinko, is, well, what -- what type of system would

Actelion have to put in place to make sure the drug that it is manufacturing, this is Actelion's drug, that's being administered to patients, to make sure it's done in a safe and effective manner. For example, reviewing the protocols that the generics have used for their BE testing, confirming that the generics are actually able to comply with those protocols, and monitoring, as Actelion does itself with its own distribution system on a daily basis, monitoring the use of the drug and the administration of the drug in the protocols.

The question is, does the law obligate Actelion to take that burden on? Now, there are potential alternative -- there are potential alternative ways to approach it. You could, for example, have the FDA review the protocols for compliance, the generic protocols, for compliance with the REMS and the restricted distribution program to make sure that the appropriate safety safeguards are there. That could be, I mean, we have -- we have told the defendants that if they were able to get that type of assurance from FDA and we really need confirmation from the FDA that their protocols met the safeguards and, therefore, we could supply under our REMS, then we might be willing to do that under appropriate terms and conditions in the supply agreement.

But with the exception of Apotex, who does have such a letter, there is no such letter from the -- from the FDA to any of the defendants in this case. That's a significant

countervailing difference between a case like this one and a case like Aspen Skiing.

And I'll note, you know, actually, your question brings to mind the Second Circuit's opinion in the Elevator case, where one of the issues was how the elevator companies had designed and set up their products so that people had to deal with them for their own elevators, for parts and for service and for other issues. And this is on a motion to dismiss, and the Court noted in considering the -- the refusal to deal case, I mean, the Court first said, "Look, there's been no history of dealing here." So that alone, which the Court characterized as the sole exception to Trinko, that alone is enough to get rid of the case.

The Court also said, and this is at 502 F. 3d 47 and 43, "Here, obvious commercial interests would justify a competitor in assuring its own control over the maintenance of the elevators it markets because maintenance is important in upholding the product's reputation for reliability and safety. No small consideration when it comes to elevators." And it's certainly no small consideration when it comes to pharmaceutical products, either.

THE COURT: Well, I have to say, I have some sympathy for the notion that -- I'm going to assume, for present purposes, and I think it's a fair one, that the REMS program mandated by the FDA and implemented by your client, it was

intended for safety purposes and not in and of itself a restraint of trade. But here you didn't -- your client did not say, "I won't sell to you unless you go to the FDA, get their approval for me to sell it to you, and approval for your protocols, and, by the way, you're going to have to pay for all that -- pay for that. I'm not doing it." You simply said, "We're just not going to sell," right?

MR. GORDON: That's because, Your Honor -- at the time, yes. The circumstances have changed and we have actually told the defendants that if they had done that --

MS. WALKER: Your Honor, I'm going to object. He's referring to settlement communications that are inadmissible under 48 and have gone nowhere. There has been no progress made. There was an offer, it has been rejected, and these shouldn't be referred to.

THE COURT: Okay. Well --

MR. GORDON: I don't think I'm referring to it for evidentiary purposes, Your Honor. I just think it's important in the context of your question just to make sure you understand the landscape.

THE COURT: I understand, and I think I invited it, Ms. Walker, but I certainly wouldn't want to impede reasonable discussions.

But my point is -- well, if -- let me put it hypothetically. If you received assurances from the FDA that

it would not violate the REMS to sell to Apotex and the other company -- and, by the way, I have no intention of becoming a regulatory agency for the sale of these two drugs.

MR. GORDON: Good choice, Your Honor.

THE COURT: And it did give me pause when I first read Trinko that -- well, I assume that if, ultimately, that was negotiated -- a negotiated resolution or was part of relief ordered by this Court that, with the FDA -- that the contract and FDA regulation would fill that gap. Our -- if the FDA said, "We approve it, we'll set up a separate protocol for them, we'll regulate them, and we will look to them for compliance, and otherwise absolve Actelion of that obligation," would you still refuse to sell?

MR. GORDON: In that -- let me answer that in two parts, Your Honor.

I would still say we don't have a legal obligation to sell because just because the FDA blesses the protocol in that way doesn't -- doesn't relieve Actelion from the potential liability risk and the potential reputation risk. So it doesn't necessarily relieve Actelion of the need to monitor how the generics are doing in complying with the FDA. So I don't think there would be a legal obligation.

In terms of whether or not Actelion would be willing to exercise its discretion to sell in those circumstances, Actelion -- assuming the other terms and conditions can be

agreed upon, you know, there is supply chain considerations, volume, price, indemnification provisions, then the answer is, yes, we would sell in that circumstance. That is a matter of discretion in our view on our part that we are entitled to make, but Actelion would exercise its discretion in that situation to sell.

THE COURT: Well, I guess it begs the question, then why not?

MR. GORDON: They don't have a letter. I mean, the one party that does have a letter --

THE COURT: The letter from the FDA saying it would be okay --

MR. GORDON: Correct.

THE COURT: -- if you accepted samples?

MR. GORDON: To give you an example, Your Honor, you look at the letter that they cite in their materials in the Lannett case, which I think is Exhibit A to the affidavit, the declaration that was submitted with their papers. That letter that they quote in brief in their -- in their briefing, goes on at length, when it says Celgene could supply Thalomid, it requires, as a condition of that, that either the -- the protocols are submitted in what's called an IND to the FDA, or Celgene is able to get some other assurance from the agency or otherwise that Thalomid is going to be used in a manner that's safe and effective and consistent with the restricted

distribution in that case. And then it goes on for pages with direction to Lannett about specific things that have to be in the protocol to make sure that the protocols are consistent with the REMS in that case.

So if we have that type of letter, Your Honor, in this case, if we could reach agreement on the other terms and conditions of sale, yes, we would sell.

THE COURT: And --

MR. GORDON: But we don't have it.

THE COURT: From one and not the other or for --

MR. GORDON: We have it from Apotex. We don't have it from anyone else. We are in discussions with Apotex, and fairly close, but there's still a few things that need to be worked out on the other terms and conditions of sale.

THE COURT: All right. Do you have any reason to believe that -- is it pronounced Roxane?

MS. WALKER: Roxane.

THE COURT: Roxane, just like the name, like the song?

MS. WALKER: Yeah, like the song.

THE COURT: -- that Roxane wouldn't be able to obtain such a letter?

MR. GORDON: I don't know, Your Honor. I don't know. I don't know what their protocols look like. I think if they have appropriate protocols, they might be able to get it from

the FDA, but they don't have it. They haven't gotten it. They asked us for samples years ago, and we still don't have it. So the answer is, I don't know. I can't predict --

THE COURT: All right. Well, all right. All right. The -- I'm sorry. I interrupted you. You have this presentation that you wanted me to follow along and I interrupted you.

MR. GORDON: What I really want to do is make sure I answer your questions, Your Honor, so I'm happy to continue in any fashion that you would find most helpful.

THE COURT: Keep going, and I'll reserve the right to jump in.

MR. GORDON: Okay. Well, many of the slides that precede this one, I think we've covered already.

THE COURT: All right.

MR. GORDON: The slides pretty much cover the reasons why there's a REMS for Tracleer and why there's a restricted distribution program for Zavesca, the -- Actelion's concerns about the need for entanglement, ongoing entanglement, if there was going to be the supplying of samples, and another -- another point --

THE COURT: You're talking about by the Court?

MR. GORDON: Possibly. If the Court were -- if the Court were to order Actelion to supply samples and say, as a matter of law, it has an obligation to force the sale of

samples, then there's the questions of under what terms and conditions? And this is exactly the kind of thing the Court in Trinko was warning about.

So I'm not so much worried about price terms. I'm not so much worried about volume terms. Those type of things I think are pretty simple. But there are the terms and conditions related to, how is the drug going to be handled, how is it going to be administered to patients?

I mean, the Tracleer REMS requires patient questionnaires. It requires monthly liver testing of the patients. It requires training for the docs who prescribe it and for who use it. How is Actelion going to know that all of that is happening? And what -- and so I can see a lot of potential for Court entanglement in discussions about, what's that look like?

And then when it's implemented, is it being complied with? If Actelion asks for information that's related to, for example, the type of information it tracks, it looks at the patient questionnaires for all of the patients. Are the questionnaires filled out for all the patients? Is the appropriate amount -- Actelion -- Tracleer, rather, can only be supplied in 30-day supplies to make sure people get their liver testing that they're supposed to. Is the liver testing being done?

We may want information on that. We may ask for it.

I don't know what -- I don't know where the negotiations would lead. But if that's what we ended up with, was some type of like consent order providing for that, then the Court's got to end up mediating disputes over whether or not that's been complied with. And our point, Your Honor, is not that we wouldn't be able -- wouldn't be willing to potentially do this as a discretionary matter. If -- if appropriate terms and conditions could be worked out as a matter of contract. It's that we can't be obligated as a matter of law to take that burden on, and the Court shouldn't be put in the position of having to monitor the implementation of such an agreement.

THE COURT: All right.

MR. GORDON: All right. The other thing that I'll note that's mentioned on the prior slides is that, you know, we were talking about the safety issues and the recognition by the FDA in the Lannett letter of the safety considerations.

Congress also in 2012 was considering legislation, didn't pass it, that would have set up conditions regarding the sale of samples of REMS-covered drugs. In connection with that, Congress included a liability safe harbor, recognizing that if we are going to set up a system that might effectively require the sale of samples, we need to provide a liability safe harbor.

Now, the reason I mention that, Your Honor, these concerns about safety are not fanciful. They are real, and

has been recognized by FDA and has been recognized by Congress, or at least some in Congress, who have prepared that proposed legislation.

So, one of the issues -- one of the issues that the defendants bring up is that, you know, the prior course of dealing shouldn't be a sine qua non of a refusal to deal case. It was -- happened to be present in Aspen Skiing, but it shouldn't be required. The fact is the great weight of authority has required a prior profitable course of dealing in these cases. As I mentioned before, you've got cases from the Second Circuit, the Tenth Circuit, the Ninth Circuit, the Eleventh Circuit. The Third Circuit has yet to rule on this, but they did give, I think, a clue in the Broadcom v. Qualcomm case.

THE COURT REPORTER: I'm sorry?

MR. GORDON: Broadcom v. Qualcomm. That was a case that did not deal with refusal to deal. It dealt with issues of alleged fraud on a standard-setting body. But what the Third Circuit said is that if this were a refusal to deal case, perhaps it would fall into an exception to Trinko, and that's because Qualcomm had agreed, previously, to make its technology available on a reasonable and nondiscriminatory basis. So there had been a prior agreement. The problem is, with Qualcomm's conduct is that they had engaged in fraud on -- at least allegedly, on the standard-setting body.

So the point here, Your Honor, is that it's fairly well established that the prior profitable course of dealing is that dividing line between -- on a refusal to deal case, between a legitimate refusal to deal, a monopolist's legitimate right not to have to set up a competitor to eat away its customer base versus that and the kind of fairly egregious conduct at the outer bounds of Section 2 liability that was present in Aspen Skiing.

The other thing is that there was some suggestion in the briefing that Trinko should be limited to industries where a regulator can force access, because in Trinko, the Court, particularly dealing with the essential facilities doctrine, said, well, here we have a regulator and we have legislation that allows the regulator to enforce rights of access, so, therefore, we're going to back off on the essential facilities doctrine. There is no need to apply it here. We questioned it, but there was no need to apply it so it didn't repudiate it.

The fact is, if you look at the cases that apply refusal to deal law since Trinko, they involved numerous industries that have no regulation whatsoever or very limited regulation. You've got handheld devices, you've got elevators, physician services, et cetera.

And the Second Circuit, actually, in that Elevator case that we spoke about a moment ago, actually explicitly

rejected the argument that Trinko would be limited to cases where there was a pervasive regulatory scheme. So it considered that and rejected it.

Now, you asked at the start, Your Honor, why not discovery? Why not discovery in this case? Aren't they entitled to discovery? And our view is here there's no need for discovery. There's no -- there's no voluntary long-term course of profitable dealing between these parties; quite the contrary. There would be the need to set up exactly the kind of systems and monitoring and compliance for the protocols that the Court in Trinko expressed concern about, which would implicate not just -- not just Actelion but also, potentially, if there was a consent order or -- or an order forcing us to deal with them, would potentially implicate the Court.

And against that, the countervailing issue is that there is objective, really indisputable fact of the safety risks that are involved in these drugs. So there's really, in this context, much like Elevator, much like these other cases, no need for any further discovery on these issues.

The other issue in terms of why there should be no discovery in these cases is that Tracleer, at least with respect to Tracleer -- Zavesca was patented until June of 2013. June of 2013, the Zavesca patent expired. Tracleer remains patented. There was absolutely -- there's no basis to force, under Hatch-Waxman, under the REMS statute, under the

Sherman Act, there's no basis to force Actelion to sell samples to the generics to begin with. There's certainly no basis to vitiate Actelion's patent on Tracleer and force Actelion to basically -- or to transgress kind of the core of Actelion's patent rights which is to decide who it wants to sell a patented product to.

The plaintiffs made reference to the Bolar amendment, Your Honor. They talk about the Bolar amendment being -- making patent rights irrelevant here because under the Bolar amendment, the generics are permitted to use patented compounds for the purpose of testing to do an ANDA. I don't disagree with that. But nothing in the Bolar amendment strips a patentholder of its right to decide it doesn't want to sell its patented product. There is nothing in the Bolar amendment that does that. It's a very narrow exception that Congress enacted in the Bolar amendment.

And I think the language from the Independent Services case is really -- is right on point. This is a situation -- this was a situation where a number of operators or Independent Service Organizations were complaining that Xerox wasn't selling patented parts to it so they could compete with Xerox in the servicing of Xerox copiers. The Court said, we can't -- we're not going to force a patentholder to provide the patents. And, by the way, there's no reason to inquire as to the subjective motivation of Xerox

to refuse to sell or license its patented works. These are patented products.

Just briefly, Your Honor, I just want to touch on the essential facilities doctrine because it's something that the generic defendants argue is another route around the right of a party to choose with whom it's going to deal. A few points on the essential facilities doctrine.

Number one, it's a doctrine that's frankly on life support after Trinko, but Trinko did not repudiate the doctrine. Some lower courts have questioned whether or not it's still valid after Trinko, but it has not been repudiated.

But even if it's a valid doctrine here, it just doesn't apply. If you look at the essential facilities cases, cases that the generic defendants cite, they are cases that involve the potential for extending or transferring a monopoly from one product or one market into another product for another market because the alleged monopolist controls some infrastructure or network or facility that's necessary, so -- power transmission lines or stadium for holding concerts or other venues. So the situation is one where the alleged monopolist who provides and promotes concerts and sport events won't let others in to compete in the market for promotion because it controls the stadium.

THE COURT: Well, why couldn't you characterize the markets here as being prepatent, pre-expiration exclusivity as

one market, and post-expiration, premarket, one assuming the entry of generics? In other words, couldn't the separate or different market, even if that's a prerequisite for an essential facilities claim, couldn't the market be the one that exists before the patent expires and the one after? Because what --

MR. GORDON: It's the same --

THE COURT: The problem here is -- or the concern, I think, would be that the refusal to sell samples, coupled with the very restrictive -- the exclusive distribution agreement, indeed, the banning of sales, unapproved sales, coupled together, mean that the patentholder is extending its patent into the expiration period at patent level prices because it's effectively excluded any generic competition?

MR. GORDON: Your Honor, I think --

THE COURT: Isn't that the -- isn't the second market post-expiration?

MR. GORDON: No, because you're still talking about the same compound, you're talking about the same drug. And the generics have alleged the market to be, in the Tracleer case, a market for bosentan, that that's the market. And what they want is they want the very product -- they want access to the very product that they want to test, copy, and then introduce into that market to compete with Tracleer. So it's not -- I hear the question about the kind of -- it's almost a

temporal dimension --

THE COURT: Right.

MR. GORDON: -- to the market. But that's not what the relevant market is here that's been alleged. The relevant market that's been alleged is a market for bosentan.

And on the essential facilities, Your Honor, I will also note that -- we have the same patent issue, at least with respect to Tracleer and with respect to the Zavesca, at least up until June of 2013, is that no case has ever held a patented technology or product to be an essential facility. And, in fact, cases have held to the contrary. Because to do so would basically be using the essential facilities doctrine to vitiate a core right of the patentholder. But the patent brings with it the right to exclude.

THE COURT: There's no question that there's a tension there. But as the -- down the road, assuming that the Court allows the counterclaims to go forward, the viability of that claim or that theory might be mooted by just a plain, clear finding of Section 2 liability, right?

MR. GORDON: I don't think there could be -- I mean, the conduct that's being complained of is the refusal to supply the sample and the sample is patented. So I guess my point is there can't be Section 2 liability for refusing to provide a sample, a patented product to a defendant. So there's no basis. That's the only conduct that's alleged in

this case.

THE COURT: Right.

MR. GORDON: I think one of the things -- one of the things you're putting your finger on, Your Honor, which is definitely an issue here, is the generics argue that the -- there's a tension here. We argue we have a right not to -- to choose with whom we want to do business and not to do business with rivals that we don't want to do business with and have never done business with. And they say that's in tension with Hatch-Waxman and the Hatch-Waxman policy.

The problem is that there's nothing in Hatch-Waxman, there's nothing in the REMS statute that creates -- that abrogates the right of even an alleged monopolist to decide with whom it wants to do business. That's a basic tenet of commercial and economic freedom. There is nothing in Hatch-Waxman that abrogates that right.

THE COURT: It doesn't, but doesn't it assume -- doesn't the regulatory system kind of assume that samples will be obtained in the normal course?

MR. GORDON: Well, here's the thing. I mean, when the regulatory system was set up, before REMS was put in place, before these restricted distribution plans became more of an issue, this -- when Hatch-Waxman back in '84 was passed, this wasn't an issue. It's not an issue outside the REMS and restricted distribution context because the generics do get

samples on the market from wholesalers. So it's not in that situation.

But nothing has been done, and I don't think antitrust is the place to do it, to -- if there is a tension here between this right with whom you're going to do business and the Hatch-Waxman policy, to resolve that tension. If there's a tension there, the place to resolve that is Congress.

THE COURT: Well, I agree with that. I was about to say, this would have been a lot simpler if Congress had just simply said at some point or obligating what I guess was an assumption or at least contemplating what might happen when REMS became more prominent as a result of products liability issues. The briefs tell me that 40 percent of new drugs are REMS controlled?

MR. GORDON: Well, that number, Your Honor, I mean, REMS come in different flavors. REMS -- not all REMS include elements to assert safe use. And I don't know what the number is of REMS that include these kind of restrictions that are at issue in this case.

THE COURT: It just suggests that if Congress had thought about it, you would think they would have said, well, we have Hatch-Waxman and it's beneficial and it's struck this balance and the world has acclimated to it and drugs are being distributed at reduced prices for the benefit of all, the

research still is ongoing and brand name companies, all of them seem to be making profits. It's a wonderful balance.

But then to allow the FDA to -- or in the face of increased regulatory scrutiny of dangerous drugs, to not provide a remedy if it had the unintended consequence of rendering 40 percent of the market unsuitable for Hatch-Waxman, that they would have responded in some way. This strikes me as something that Congress could have and should have fixed.

MR. GORDON: And --

THE COURT: And perhaps now -- perhaps now they should. But that -- Congress's silence on this issue, I'm concerned about the notion that Congress's silence on this issue can be read broadly to suggest some modification of Section 2.

The quote that I had pause on -- or paused on numerous times was, I guess, from Colgate. "In the absence of any purpose to create or maintain a monopoly, the act does not restrict the right of trade or a manufacturer to exercise its own independent discretion as to parties with whom he will deal."

So, inherent in that principle of law, which I think both sides agree, is itself an exception -- is present an exception to the otherwise paramount right to refuse to deal, and, that is, if there's a purpose to create or maintain a

monopoly.

And at least with regard to the patent that expired in June, the inability to obtain samples of a now unpatented product and engage in the ANDA process, at least seems to have the effect, if not the intent, the effect of maintaining the monopoly, and the prices that follow with it.

MR. GORDON: And here's the thing, Your Honor. I don't quibble with the quote from Colgate or the principle. But the Supreme Court since Colgate has further defined how Colgate is to be applied in a refusal to deal context, and most recently in Trinko. So the question is not just a broad Colgate principle. The question is how is that principle affected by the decision in Trinko under which the Court said the one situation, which is at or near the boundary of Section 2 liability where we will find a refusal to deal might give rise to an antitrust claim under Section 2, is Aspen Skiing and the Aspen Skiing exception which involves a long-term profitable course of dealing, and that is a decision that has then been echoed by numerous appellate and district courts since Trinko.

So I think you start with Colgate, but then you have to ask, well, what has happened to the Colgate idea since? And, most recently, we have Trinko and then the Courts interpreting Trinko.

I want to come back to a point you made about

Congress and the generic defendants --

THE COURT: I've already gone farther than I like to go. Don't bait me anymore.

(Laughter.)

MR. GORDON: Okay. They did manage to get us back in business, though, Your Honor.

THE COURT: Did they?

(Laughter.)

THE COURT: They tell us till Friday.

MR. GORDON: So the defendants argued that this language is, you know, the so-called (f)(8) language that says that "No holder of an approved covered application shall use any element to assure safe use to block or delay approval of an application," that that operates as something abrogating the right of a company to choose with whom to deal. And the fact is it just doesn't. It doesn't say that in there.

Congress, regardless of where you come out on Congress, certainly, folks in Congress are capable of saying, if they meant, branded companies have to supply the product samples to the generic. They're capable of saying it. And how do we know that? We know that because they did, or at least some in Congress in the proposed legislation in 2007 actually included language in draft legislation that says that, "A branded company shall provide to such a sponsor, the generic, a sufficient amount of drug to conduct bioequivalency

testing if they agree to the restrictions that the FDA finds appropriate."

Now, Congress didn't pass that, and the reason I raise it is not because I think -- not because I'm suggesting Congress somehow rejected that and that has the force of law. The reason I suggest it is it's evidence, and I think displays that the folks in Congress are capable of saying you have to sell if they mean you have to sell. And they did it again in 2012 with the amendments that were contemplated in 2012. Again, the language was very specific and it was very clear that it was meant to set up conditions that would require the sale of samples under certain conditions to a generic. So when that's what they meant, that's what they said.

THE COURT: Well, I agree with you that that provision doesn't say -- that is not an obligation to sell, can't be fairly read as that, and that if it was intended to say that, it would have used the language in the failed amendments.

But what I'm having difficulty is extracting from that the notion that that somehow would allow a brand name manufacturer who has, I will call it, Section 2 intent to absolve -- to confer upon them some kind of Section 2 immunity where other -- conduct beyond a mere -- beyond a mere refusal to sell suggests an intent to extend or maintain a monopoly.

MR. GORDON: And here's the thing, Your Honor.

Trinko has told us, has defined for us the circumstances under which you could possibly infer the type of intent that you're talking about.

THE COURT: Only prior course of conduct.

MR. GORDON: Only prior course of conduct.

THE COURT: I don't know.

MR. GORDON: And that's what the case --

THE COURT: I don't know if Trinko goes that far.

MR. GORDON: Well, that's the way the cases that have interpreted Trinko since Trinko have said. And I'll tell you, there's certainly a logic behind it. I mean, Courts have developed tests in a variety of areas of antitrust law that are intended to be objectively verifiable tests to make sure that we are not getting false positives, so you're not ending up with antitrust law which is a fairly blunt hammer being used to come down on companies, even alleged monopolists who are doing things that are perfectly appropriate.

So the predatory pricing test, for example, where someone is alleged to have priced below cost in order to drive out a competitor, well, low pricing is beneficial, it's perfectly appropriate. So how do you define the line between anticompetitive low pricing and regular, appropriate low pricing? The Courts have come up with an objectively verifiable test to do that.

Here, similarly, Courts have said that, look, if you

don't have a prior course of dealing suggesting that the monopolist has changed course to pull the rug out from under a competitor, a monopolist doesn't have the obligation to set up competition next-door in order to take its -- its business. It doesn't have that. It doesn't have it under Trinko. It doesn't have it either --

THE COURT: I agree with that.

MR. GORDON: Yeah. So --

THE COURT: But that's not what they allege here. They allege more than -- they're not alleging you have to help us.

MR. GORDON: That's exactly what they're alleging, Your Honor.

THE COURT: They're saying you can't put in place -- you can't couple your refusal to sell with other market restrictions that frustrate our -- I will call it a right. I guess it isn't a right, but our ability to enter the market under the provisions that Congress has created.

MR. GORDON: But those other market restrictions, the REMS, they were required by FDA as a condition of approval. Those aren't things that we just decided to come up with on our own. I mean, frankly, no drug company wants to have to operate under our REMS. It's onerous, it's difficult, it requires constant monitoring and auditing.

So those were things that the FDA -- and not to

mention the fact, they were reviewed by FDA. This is what FDA does. It reviews how drugs are distributed. It reviews the conditions that are put on the distribution of drugs. So that conduct, frankly, is Noerr-Pennington protected.

THE COURT: And I should rephrase the question because -- rephrase the question, because it's not, I suppose it's not so much the restrictive agreements -- maybe they go so far to allege this but it's -- it's the refusal to deal -- the refusal to sell in the context of a regulatory and -- and practical market that otherwise precludes their access to it. It's not so much that -- or it might not be so much that REMS, that they fault you for complying with REMS, as it is taking advantage of REMS to justify what would -- might otherwise be intended anticompetitive conduct, that is, the refusal to sell the samples. You have the right not to sell. But if you say that in the context of knowing there's no other way they can get it, it takes on a different hue. It takes on a different -- it may take on a different meaning under Section 2.

And if I accept the principle that prior course of conduct is not necessarily required, at least until we learn more facts, then the question for me becomes: Is that enough?

Let me ask you this: When your client engaged in its own clinical trials for the Tracleer product, what was the role of the FDA in helping design a protocol with -- for those

trials?

MR. GORDON: The FDA, I mean, as a sponsor of an NDA, I believe, and I haven't -- I believe that Actelion would have had to file an INDA, investigative new drug application, with the protocols, so the FDA would have an opportunity to review those protocols in connection with the -- because they would require the administration of drugs in humans. Go ahead.

THE COURT: I was going to say, I guess we went over this, but I guess there's no reason to believe that the FDA couldn't similarly do that if that ultimately was a remedy if the defendants prevailed on their counterclaims.

MR. GORDON: There's no reason -- well, regardless of whether they prevail on their counterclaims, there's no reason to believe FDA couldn't do it, could not -- could not review the protocols and deem them to be consistent with the REMS. In fact, there's one instance in which they have done that, in this case.

The last thing I'll mention, I just want to say one last thing because we haven't really talked about the Section 1 claims, the claims that are based on the distribution agreements.

THE COURT: Right.

MR. GORDON: And the only thing I'll say on those is that it's really old wine in new bottles. I don't think the Section 1 allegations add anything new to this case. There's

no allegation that the agreements themselves are any broader than what was required to implement the REMS program. And, frankly, the implementation of the REMS and the conditions that Actelion put on distributors to comply with the REMS is a unilateral condition that's imposed by Actelion.

So I just mention that because, from my perspective, the Section 1 issues and the Section 2 issues conflate. It really comes back to the question of Actelion's right to choose with whom it does business and whether or not, under these circumstances, that right requires any additional discovery, and we, for the reasons we've talked about, would submit that it does not.

THE COURT: Well, I guess I agree with you, only to the extent I looked at it from a different perspective, or at least it could be argued from a different perspective that if I decided Section 2 claims have been adequately pled, then I don't -- I could reserve until later as to whether or not Section 1 actually represents a standalone claim or whether some of the defenses that have been raised to it would -- you know, whether there's a unity -- whether there's separate, independent economic actors and the -- whether or not it's a contract per se or a unilateral imposition of a condition on the other defenses. It seems to me that they are closely related, they are interdependent, and if I were to allow the Section 2 claim to go to discovery, then I would probably

reserve on the motion to dismiss the others until there was more factual development.

All right. Anything else?

MR. GORDON: Nothing else, Your Honor, unless there are any other questions you have.

THE COURT: I do have one, but I can't -- it's on the tip of my tongue, so I'll think of it.

MR. GORDON: I'll be here.

THE COURT: All right. Who --

MR. GORDON: Thank you, Your Honor.

THE COURT: -- wishes to be heard for their client?

And so it's accurately reflected, if you could restate your name.

MR. GOELMAN: Aitan Goelman on behalf of defendant/counterclaimant plaintiff Apotex. Good afternoon again, Your Honor.

THE COURT: Good afternoon, Mr. Goelman.

MR. GOELMAN: Counsel for Roxane is going to take the lead and has a very pretty PowerPoint presentation that she's going to guide the Court through.

I just ask to be able to address the Court momentarily, before she begins, to address one question and answer between the Court and counsel for Actelion, and, that is, when the Court raised what it termed the hypothetical situation of a generic which has a letter from the FDA,

explicitly approving the safety in its bioequivalence protocol, what Actelion would do in those circumstances.

And, indeed, it is not a hypothetical. We have the answer because it happened. And it happened in May, Your Honor, where Apotex received from the FDA Office of Generic Drugs explicit approval for its bioequivalence protocol and the safety standards that were articulated therein.

And, immediately after getting that, we sent a letter to Mr. Gordon attaching the approval from the Office of Generic Drugs and reiterating our request for the samples and noting that if Actelion refused under these circumstances, that would prove that its citation to the REMS was nothing but a pretext.

And our answer came 22 days later, when Mr. Gordon, on behalf of his client, said, "This changes nothing. You don't get it." And that was in May.

So, for the last five months, Your Honor, at $100 per day per patient, $15,000 per patient over the last five months, Actelion has been able to exploit those monopolist profits.

And I don't have a copy of these -- of this correspondence, but I know Mr. Gordon has a copy, so I would, if the Court is interested, ask to have these marked as an exhibit and tender them to the Court.

THE COURT: All right. I'll ask Mr. Gordon whether

he cares. I have a motion for judgment on the pleadings and a 12(b)(6), so we are perhaps going far afield of that. But I'm happy to receive them if Mr. Gordon doesn't object. But, ultimately, the question here is what's alleged so far. Correct?

MR. GORDON: I don't object because -- to the extent I think they are irrelevant. I mean, if you want to -- what Mr. Goelman doesn't mention and -- is that Actelion later got communication directly from FDA, much later than these letters.

And, as I mentioned before, our position is not that if the FDA provided such a letter, Actelion is obligated to sell, because Actelion doesn't believe it is because, as you will read in the letters, Actelion believes that it would have an independent obligation to make sure that the drugs are being administered appropriately.

But since then, there's a lot of water under the bridge. We received a communication from the FDA which I don't have with me. And we've also communicated to Apotex that, in light of the current circumstances, we are willing to provide samples under what we would deem to be appropriate terms and conditions, and, in fact, we're pretty close to getting there. So there's a lot of context that has to go along with these letters. And I don't know that it's either here nor there for purpose of the current motion.

THE COURT: All right. Well, I'm happy to take them, Mr. Goelman, if you want to hand them up.

MR. GOELMAN: Thank you, Your Honor. May I approach?

THE COURT: I appreciate you providing additional information and clarity on the issue that I had raised.

MR. GOELMAN: (Complies.)

THE COURT: All right.

MR. GOELMAN: Your Honor, I'm going to just let counsel for Roxane take over.

But I do want to note that the issue that is presented in the motion for declaratory judgment doesn't have anything to do with REMS, and you can see over and over again in Actelion's briefing that they claim a very absolute right to not provide samples and that doesn't have to do with REMS. To say that this is -- we may, in our discretion, provide samples if we want to, but what branded pharmaceutical company in their right mind, if they have this absolute right, if the Court were to sign this declaratory judgment that Actelion has requested, what branded pharmaceutical would ever allow a generic competitor to obtain the BE samples necessary to bring a generic competitor to market when we know the statistics, that basically the monopoly profits almost immediately dry up when there's a generic entrance into the market.

THE COURT: All right. Thank you, Mr. Goelman.

MS. WALKER: And I do have pretty slides. However,

it's also evident that we've covered some ground and the Court is familiar with the brief, so I don't feel that we'll have to be looking at all of them.

THE COURT: All right. Could you just give me one minute while I reflect on something?

MS. WALKER: Absolutely.

THE COURT: All right. Can I leap ahead a little?

MS. WALKER: Excuse me?

THE COURT: Can I lead ahead and ask you a question?

MS. WALKER: Leap away, Your Honor.

THE COURT: All right. What about -- does Trinko tell me that refusal to deal requires a prior voluntary course of conduct?

MS. WALKER: Absolutely not. Trinko noted the prior course of conduct by the Ski Company to explain -- essentially there's something going on here anticompetitive. There's no unqualified right to refuse to deal. If -- but the reason that you -- it is often perfectly lawful to refuse to deal is there may be valid economic business reasons for the monopolist to do so.

What Trinko was analyzing -- and you can tell it wasn't just based on the course of conduct because they also cited the pricing and said it was suspicious that the unwillingness to accept the standard retail price was also indicating that there was something going on here in terms of

predatory behavior.

And, in fact, even though, yes, some courts since Trinko have said, oh, they talked about course of dealing, being Aspen Skiing, does that mean you always have to have a course of dealing? Some have said yes, but some have said no.

And, certainly, the Third Circuit, we would contend that there is no law requiring course of dealing.

And, in fact, the Helicopter case that we cited, Your Honor, states it best, that says, "The Supreme Court has never" -- this is post Trinko -- "The Supreme Court has never held that termination of a preexisting course of dealing is a necessary element of an antitrust claim. It was merely one of several facts in Aspen Skiing that supported a finding that the refusal to deal was intended to exclude competition rather than to advance a legitimate business interest."

And that's what the generics have alleged here, Your Honor, that there is -- there are all kinds of similar indicators. The generics have offered to pay retail published price or, frankly, you know, any price that was within the realm of reasonableness, they would pay.

Also, the generics have pointed out, have alleged and it is not disputed, that clearly, the drug has been sold to other research organizations, which is yet another indicator, like the prior course of dealing in Trinko that says there is predatory conduct going on here, there is something going on

other than a legitimate business interest given that they're willing to sell it at retail price to distributors, specialty pharmacies, and they're apparently willing to sell it as well to other research organizations who are not within their REMS publications.

So it's a bit longwinded, but the answer is, no, post Trinko, it is absolutely true that you need to have some sort of indicator that there's not a business, legitimate business rationale, but any one of these things can serve as one.

And in a prior course of dealing, as well, I point out, it's really narrowing it to say it's got to be a private course of dealing between Actelion and Roxane. If they have a prior course of dealing to sell to other similarly situated people as us, that's still a prior course of dealing. So even if you look at one of the cases that call it a prior course of dealing, they could be extraordinarily narrow to say it has to be the exact same two people involved.

THE COURT: All right. Thank you.

Back to the slides.

MS. WALKER: Well, I'm kind of deviating from the slides. I'm not going to put it up because that's not terribly convenient for the Court, I think, anyway.

But where we are, to go back to one of the first things that the Court asked about, this being a Rule 12 motion, all of the generics' allegations have to be accepted

as true, and all of the issues and the issue of handing up the letters Mr. Goelman gave you, the point is, we have alleged these things, and if allowed to go forward, the discovery will show these things.

The discovery will show -- whether those letters are in the record or not now is irrelevant. The point is the discovery will show that these things are happening. The discovery will show they say, "No, we don't have to sell to you. We don't care. I don't care what you come to me with from the FDA. I have an absolute right to sell," and maybe even conceded here, they have discretion. Maybe in their discretion, they'll sell. But they're not going to ever admit that they have to make this happen.

And one of things that we have to look at is what have the generics pled here? This case has been oversimplified a little bit in Actelion's briefs.

The generics have pled an actual claim. First, because we've absolutely pled all the elements under Section 2 and Section 1. Second, we have pled far more than any refusal to deal here. We have pled that they are refusing to sell it but it's more than that.

Frankly, we don't want to buy from Actelion. We really don't. This is not how the generic industry works. We are trying to introduce competing products to a brand name product. We don't want to go knocking on the competitor's

door and say, "By the way, we're thinking of developing a generic version of your product." That is not how it works in the vast majority of cases in terms of generic products that are developed and that ANDAs are filed for.

What normally occurs, you would never want to go to the manufacturer. That would be the last thing you'd want to do. What you would rather do is go out and buy from a wholesaler, distributor, and even the normal channels. And this is absolutely allowed. The generic companies have licenses from state pharmacy boards that authorize them to buy prescription drugs, controlled substances that ordinarily, obviously, people just can't go out and buy. So they can -- you know, drugs can be distributed either to patients by going to pharmacies and being sold to patients pursuant to prescriptions that way, or, obviously, Roxane, as a company, doesn't have a prescription for a drug. It has a authorization, a license, as a research organization, to purchase these drugs.

So, ordinarily, we would go to whatever the wholesaler or distributor or specialty pharmacy that was selling these products was, and we would buy from them, and that would be vastly preferred. And, in fact, we do so in many cases, both in non-REMS situations and in REMS situations.

And these -- let me tell you, these distributors

would like to sell to us. In all these cases where REMS have come up, where we've had trouble getting a drug, the distributor -- I mean, it's more sales, more money to them. They would love to sell to the generics. And they often -- evidence will show, if the case goes forwards, they often have to say, "Oh, sorry," you know, many times, the order has gone in and then the distributor has to come back and say, "Oh, sorry, I can't because I've been restricted through this agreement with the brand."

So that is -- the whole idea that they're being forced to sell when they don't want to is really a red herring. There have been numerous cases, just on behalf of my client and each of the other generics has similar ones, as well as other generic companies, many of these REMS situations have been resolved. And they've been resolved either because the company chose Path A, which was to sell to the generic specifically, or B, they said, okay, you know, they made it clear to the distributor that the distributor was allowed to sell. So they could take either path.

So it's really a lot of background, and certainly some of it may be outside the pleadings, but I want to stress that those -- that is the evidence that will be shown if this case goes forward and there is discovery and there is evidence being introduced. We have alleged these things, we have alleged a broader scheme in restricting the ability to

purchase these drugs, and they are sufficient.

Second of all, even if you just focus on refusal to deal, we've talked a lot about Trinko, et cetera. We've pled more than a refusal to deal. But even if it's just refusal to deal, there is no immunity for refusals to deal. And we have alleged actual facts here and the discovery would show that.

For example, the REMS, it defies logic when you look at all the aspects of the REMS to say that somehow this is forbidden under the REMS. When Congress passed the REMS, first of all, you've seen the clause that we've all cited to, saying, "You cannot use this, Brands, to block or delay generic approval." And, you know, I'm not going to go through all the slides, but I think one of the slides that's kind of interesting is Number 8, because this is exactly what's going on.

Number 8 is from a presentation that was -- and this is alleged in our complaint. These allegations are in our complaint. REMS is a tool for profitability. What has been happening, if the clause is not interpreted correctly, it says -- the FDA says, you cannot use REMS to block or delay a generic, then, as Mr. Goelman stated, every brand company is going to say, "Ah-Hah, I'll just pass a REMS and that way, I can basically block the entire Hatch-Waxman statutory framework because no one will ever even be able to file an ANDA because no one will ever even be able to do a

bioequivalence study."

In addition, the FDA -- the Lannett letter was mentioned before. Well, what the FDA said there is broader than any issue about the protocols was, quote, "It is not the agency's intention to permit the restrictions of the REMS program to prevent manufacturers of generic drugs from obtaining that drug for use in bioequivalence testing necessary to obtain approval of an ANDA."

Moreover, another fact -- and this sort of leads into why the whole FDA role has been misrepresented. The FDA issues guidances, and it issues them specifically in the context of drugs that -- that they anticipate generics may wish to develop. So the -- on the FDA website, you can look it up, take judicial notice, et cetera, and it's in Slide 5, I believe, the FDA has bioequivalence recommendations for specific products. 5 is the statute. I'm sorry. Has a -- the FDA has published guidances for specific products. And the guidance says, "These are the protocols you have to have for bioequivalence studies on REMS-covered drugs."

I'll find that in a minute here. Find the slide that has the -- the guidances.

Specifically, the FDA here has already issued such guidances for two of the drugs here. Okay? So the FDA has published a guidance, it says, "Dear generics, here are the protocols that you have to do to develop a generic product."

That makes no sense if the FDA's position is we can't get the drug.

The FDA has said, "This is the protocol, do your bioequivalence testing in conformance with this. This is a safe way to do it."

Specifically for the Tracleer one, it says, "Due to the risk of teratogenicity of bosentan, the study should be conducted in healthy male volunteers. Tracleer was approved with a risk management [sic] and mitigation strategy which restricts its use. All pertinent elements of the REMS must be incorporated into the protocol and informed consent."

So this is how it happens. The FDA issues a guidance, says, "Do all this, comply with this, Generics, incorporate all pertinent" -- that's Slide 33 of the guidances that I'm referring to -- "Incorporate, Generics, all pertinent elements of the protocol and informed consent and go forward and do this."

And what the evidence will show is this is the way that the FDA proceeds. There is no regulatory pathway to do it their way. There is no regulatory pathway to go in first and say, "Hi, I'm thinking of doing my BE study this way. Would you bless it?"

There have been limited numbers of times that has been done lately because of the vast REMS abuse where companies have been so desperate, they've gone in and gotten

some of these letters in certain situations from the FDA or because a brand may have been negotiating with them and said, "Well, if you get the letter, maybe I'll send it to you voluntarily." But that's not how the process works.

And, in fact, if the case goes forward, the discovery will show FDA officials have screamed at representatives of our clients saying, "How dare you come in here demanding all these reviews of protocols prematurely. We don't have the staff to do it. There is no regulatory pathway to do it."

There has been talk in response to citizens' petitions, et cetera, that perhaps they'll set something up, but there is nothing there, because that's not the way they do it.

In fact, what they have -- what the evidence would show is that when generic companies have gone in to try to get that, if there is already a guidance on the books, FDA will say, "No, get out of here, we've issued you a guidance. We are not going to undertake the burden of reviewing one-off protocols." So basically, what they've suggested, and by the way, as Mr. Goelman already pointed out, rejected anyway, is not the way that the generic approval process works.

And it certainly makes no sense to say that FDA has mandated that we can't get the drugs, when FDA has put on the books a protocol that we are supposed -- that is inviting us to follow and develop the product. It certainly makes no

sense whatsoever.

Now, let's talk about what we're going to do with the drugs. Okay? Because the first round of what you have to do in a bioequivalence study. What you're trying to prove is that the generic version is chemically equivalent, basically -- I'm oversimplifying all the statutes, but basically is the same as the brand.

The first round and the vast majority of the actual product that you would use as samples are for lab testing. You do tests in labs in test tubes and dissolution studies and things that don't involve giving this to patients whatsoever. So there's no safety issue implicated there. This is lab testing. And of all of the quantity of product that you would need to do this, the vast majority of pills, capsules, whatever that you would use in BE studies is for the lab testing and for what are called retains. The FDA mandates that you retain a bunch of samples from different groupings of the various testing phases. A very small minority of the capsules are actually used in what's called the in vivo study which comes at the end. And the in vivo study is when you finally give it to patients.

But I noticed, you know, we were talking before about, you know, Tracleer's questionnaires and monthly liver tests and 30-day supplies. None of that matters, even at the in vivo portion, because we are not giving -- prescribing this

drug to anybody. We're not dispensing this drug to anybody. It's not going to patients who are going home and using this drug on a prolonged basis.

What happens in the in vivo testing is you have 28 subjects who take the drugs and have blood drawn, and that's all that happens. So you wouldn't need 30-day supplies of everything. They're coming in and they're having the -- usually what they called a two-way crossover, so they're going to be administered the drug twice. And you test them there and you take blood samples, and that's all that's done.

So a lot of this stuff about all of the -- the other aspects of Tracleer, when you're talking about patients and prescribers, simply are inapplicable when you're talking about bioequivalence testing.

And, in fact, what the FDA has you do, there's already an established procedure for this, you can do your in vivo testing and when you are ready, when you get to the point of doing -- you do the in vitro -- excuse me, the lab testing first. When you're getting ready to do your in vivo testing, you have to have an institutional review board form that reviews all your protocols, reviews your informed consents, makes sure you're complying with all of the REMS requirements if it's a REMS or restricted distribution drug. All that is already built into the process, Your Honor. That's the point.

So, based on that, the generics have alleged a

Section 2 case, and they have alleged a Section 1 case. The refusals to deal issue, even if you're ignoring the restrictions on the distributors which are key and absolutely take this out of the realm of a refusal to deal, are -- we are more like, as Your Honor stated, Otter Tail and Aspen Skiing than Trinko. The allegations that we have made and the FDA prohibition clearly show that we're more like Aspen Skiing and not Trinko.

The elements of our Section 2 claim are the possession of a monopoly power in the relevant market, willful acquisition and maintenance of that power through exclusionary conduct which means, as the Court held in Broadcom, Third Circuit case, as a result of competition on some basis other than the merits. And that "other than the merits" point is what -- what leads to these different issues that the Courts in Trinko and afterward are looking at. Is there something that -- that is not competition on the merits? Okay? Is there something else going on?

And that's why we talk about course of dealing, not accepting a retail price, being willing to sell to one research organization, then not another. All of those things are indicators that what's really going on here is just an attempt to forestall competition solely by not selling or allowing sales by others to be made, again, by generic companies.

And I would point out that this is only, as far as we know, the third case in the country where one of these REMS abuse cases has been litigated.

There was the Lannett case that's already been -- that's been settled, in which, by the way, the Court denied the motion to dismiss, as we point out in our briefs.

There was a subsequent case -- there was this one and then there's a subsequent case in Florida that has been since resolved, I believe resolved as to everybody, to my knowledge.

THE COURT: How was that -- at what stage was that resolved?

MS. WALKER: It was resolved before motions, Your Honor. It was shortly after the complaints, the brand company basically agreed to sell.

THE COURT: Okay.

MS. WALKER: And without a requirement of FDA approval, I might note.

And so there have been -- meanwhile, we've seen that 40 percent of the drugs have REMS. Why do they have REMS? Why are there so many? Because of the slide you saw before, brand companies realized, hey, this is a great -- this is a great scheme. We can keep anybody from getting a sample. We can keep ANDA from ever being filed.

And that's interesting because what was said before is it's really not the current state of play. When REMS

began, the FDA was imposing REMS and saying, in very specific cases, that the REMS was needed. Over time, though, there has been a proliferation of REMS which are voluntary, proposed by the brand. The FDA isn't imposing it on them. They are coming in and saying, "Here you go." And the FDA, if you look in -- we've got a few documents that they have attached, but if we go forward and engage in discovery, what we're going to see is this is a one-way street.

The brands are coming in and establishing this procedure and saying, "We're going to have this restricted distribution plan," but you see what the FDA is focusing on, even in the documents they've attached, the FDA is focusing on patient issues. If you look at what they call the safe elements of use, it's all about, you know, prescribers and patients and testing of the patients. None of it has anything to do with research organizations. As a matter of fact, we don't think, if you read these REMS, it even applies to us at all. It clearly applies to patients, which is not what's going on in the bioequivalence studies at all.

THE COURT: Well, let me just pause there, but the FDA does have some regulatory influence and authority over clinical trials, including bioequivalency trials, does it not?

MS. WALKER: Bioequivalence studies? Yes.

THE COURT: I mean, it would have the same concern for patient safety for someone who buys at a retail pharmacy

as it would for someone who's taking it as part of a bioequivalency clinical trial, would it not?

MS. WALKER: There are similar concerns. Obviously, any time you give a drug to a human being --

THE COURT: Right.

MS. WALKER: -- I would think the FDA would be interested in that and concerned.

THE COURT: That was my simple point.

MS. WALKER: But there is a distinct system for what might be required, when the drug goes into the sort of marketplace to be given to patients, okay? So somebody is going to walk in and get a 30-day supply of a drug that they're going to go home and use, versus a situation where somebody is sitting in a lab, they check into a research lab, and they are given one pill and then they wait and they have their blood drawn. And it's all under supervision, all these -- they're called contract research organizations. They all have to be FDA approved.

And the procedure, by the way, before -- the FDA-mandated procedure, before you can begin one, is you have to have institutional review board approval, and then you have to document that you've gotten your IRB approval before proceeding.

So, of course, there's oversight, but it's different oversight. And it doesn't mean oversight that we apply

something that's in a REMS that's supposed to apply to patient use as opposed to research use.

And, again, we would point out that it seems very strange that the studies that we cite in our complaint show that they have obviously -- the product has gone to other research organizations, you know, hospitals, et cetera, have done all kinds of research projects using these drugs, including giving them to patients, and somehow that's outside the REMS, but we're within the REMS. Why? Because we want to develop a competing product. We submit that's the only difference.

We are licensed to buy these products. We are -- we are overseen by the FDA. We are approved by the FDA to consult -- to conduct these studies. Our contract research organizations are. So we can -- we submit that it's entirely pretextual, I mean, that REMS don't even apply to us, and even if they do, they're REMS that they created and they can certainly either say, okay, then we'll sell you the drug, or we will allow our distributors to sell to a licensed research organization.

THE COURT: Well, let me just ask you something, though. In the context of you ultimately prevailing on a Section 2 claim, if I were to allow it to go forward, and you did prevail, or at any point -- at any point, what is the risk, if any, that this Court would be drawn into a regulatory

role beyond its capabilities and proper role in our system?

MS. WALKER: I would submit absolutely none because we purchase drugs all the time and have -- there's no ongoing oversight whatsoever.

Actelion keeps trying to pose it that somehow they're going to step into the shoes of the FDA. The FDA requires us to comply with the REMS. The FDA is the one who regulates us. Not Actelion. And the Court wouldn't have to do it either.

The generic companies have been buying samples and using them for years and years and years, of both REMS-covered and non-REMS-covered drugs, and there has never been some parade of horribles in terms of a brand being forced to come in and monitor what we're doing.

And, in fact, they choose to sell their drug. If this was something they were just keeping internally, that would be one thing, but they are selling it out into the market, and even the patent issues really, apart from the fact that the patent on one has expired, the patent on the other is going to expire by the time we likely get all the development work done and the ANDA approved. The first-sale doctrine says once you put something out there in the market, you can't control it further downstream. So once they sell to a distributor, a wholesaler, the patent rights cut off there. So we're allowed to come in and buy it.

But, in any event --

THE COURT: Unless it's copyright or trademark.

MS. WALKER: They haven't raised that one yet, Your Honor.

But, at any rate, no, there's been absolutely no situation, we enter into a transaction, we buy the product, we buy it at their WAC price and we go on our way.

There are obviously liability issues. If a research company didn't -- did not comply with FDA, did not -- did not administer the drug correctly or something, then we have issues, but there are no brand companies in our houses analyzing this situation. We are required to submit, pursuant to the IRB, approvals and the REMS, which we all must comply. If there is REMS, we have to comply with it. We have to submit adverse events reports to FDA, things like that. That is already required, and we do that.

So there has been -- I mean, I think we have -- the evidence will show in this case that that's completely false. There's no involvement by courts or by brand companies in the hundreds and thousands of generic products that we develop and do testing on year after year since 1984.

THE COURT: You expect that FDA letter any day now?

MS. WALKER: Well, no, because this is the problem. The FDA doesn't have a path to do that. They don't have office or staff.

THE COURT: Well, how did Apotex get one and your

client hasn't?

MS. WALKER: Because if you -- because there have been a few very difficult cases where we've been -- and there have been -- I'm aware of a few situations, I think my client has gotten two over the course of years and years of this going on. Once in awhile it will happen. Often it will happen with some, you know, real beating by -- you know, if the FDC were here, I would imagine they would tell you this. Sometimes the FDC, if it's particularly concerned about a egregious case or a really large product that is very, very expensive and has an interest in really making sure that that product goes forward, they will go and say, "Please, pretty please with sugar on top, FDA, because the brand is hiding behind the REMS, would you just issue a letter that says the REMS doesn't block you from doing that?"

So they have done that on occasion, but they have on other occasions sat on such requests for years and never responded to them. In other situations, they have told us, "No, we won't review your protocol because we've already issued a guidance, and when there's a guidance already out there, we are not going to review individual one-off requests."

And, in fact, that would be our concern here is exactly what they will do because there are published guidances on these two products already. A lot of times they

are slightly more sympathetic if there is no existing guidance, so they feel like, well, maybe you will be out there on your own, so to speak, so they might be more sympathetic. But we don't know. The bottom line is there's no regulatory pathway to do it. There's no requirement that the FDA does it. And the evidence will show that we have had -- been rejected on many occasions and just had FDA staff say, "No, sorry, it's not our job, that we are not obligated to do that and we're not going to do that."

And even if they were, how many years? How many years do you have to wait to get this so-called mother-may-I letter from the FDA that we're not required to get? We've never been required, since the Hatch-Waxman Act was enacted in 1984, to get an advance mother-may-I letter from the FDA to do our bioequivalence studies. To the contrary. It's clear that we're allowed to go forward, and the whole IRB approval process was set up so we wouldn't have to do that, so we could go forward, and when the FDA jumps in, yeah, yeah, it's not that there's no oversight. When we submit our ANDA, we submit our ANDA to the FDA, they go through everything with a fine-tooth comb, and oftentimes they come back and say, "No, we don't like these outcomes, we don't like those outcomes. We want you to do more studies. We want you to do an additional study. We want you to do more dissolution studies."

The entire ANDA approval process, from the time you file your ANDA until you actually can get it approved, I think on average runs from one to three years. So the thought that there's no FDA oversight over generic companies developing these products is just completely false, Your Honor.

THE COURT: All right, Ms. Walker, thank you.

MS. WALKER: I think I have covered most everything.

I did want to defer to Ms. Reeves on behalf of Actavis to address some of the Trinko exception issues if Your Honor has -- especially if Your Honor has questions about those, as well as on the essential facilities doctrine. Mr. Goelman is actually our specialist on those issues, but I think as to some of the overarching issues that Your Honor was curious about, I've covered those, and certainly you're welcome to flip through my pretty slides, and I won't force you to walk through them with me.

THE COURT: That's quite all right. I appreciate them and we'll have them and we'll consider them.

MS. WALKER: Thank you.

THE COURT: I would invite Mr. Goelman and Ms. Reeves to supplement the record in any way they choose at this time.

I do want to give, since it's his motion, Mr. Gordon an opportunity to respond and then we've been going awhile. Let me just see whether -- Ms. Reeves, do you have some things you wish to address?

MS. REEVES: I have some brief remarks, Your Honor.

THE COURT: All right. Thank you.

MS. REEVES: Your Honor, I would like to start, as Ms. Walker noted, by returning to the issue that this Court began with, which is under Trinko, is a prior course of dealing required?

Now, I think the Court began in the right place, which is to say that Aspen Skiing, and the discussion of Aspen Skiing and Trinko, is not focused on whether or not there was a prior course of dealing, but whether or not the termination of the prior course of dealing reflects, as Your Honor called it, a Section 2 intent, or an intent to harm competition that can be viewed differently from an intent to engage on competition on the merits.

There has been a lot of discussion of Aspen Skiing, but one case we haven't touched on that I think is quite instructive on this issue is the Supreme Court's decision in Otter Tail --

THE COURT: Otter Tail.

MR. GORDON: -- which the Supreme Court discussed favorably in Trinko. And the reason I think Otter Tail is very important on this point is the Supreme Court knows how to overrule precedent when it wants to. And it didn't with Otter Tail. And that is significant to this question because in Otter Tail, there was no prior course of dealing between the

parties. And so the Actelion's suggestion that that is somehow required is completely contrary to Otter Tail.

I also think it's useful to pause for a minute at the litany of cases that Mr. Gordon pauses on, that people, for instance, say go the other way. Now, it's true that in many of those cases, there is language that one can cherry-pick that says that there is a technical requirement that a plaintiff plead a termination of a prior course of dealing. However, I think if Your Honor looks at those cases very carefully, you will find that in every single one of those cases, they are distinguishable for several reasons.

First, in the vast majority of those cases, regardless of what the Court says about the legal standard, the Court ultimately found that there was evidence of a legitimate business justification.

So the Christy Sports decision, for example, that we discussed earlier, in that case there was a ski company -- ski companies seem to generate a lot of antitrust litigation -- who parceled out lands to third parties and when they sold the land, they basically put easements on it and said they reserved a right to approve the business plans and the conduct going forward on those parcels.

So in that case, DVRC, which was the defendant, allowed Christy Sports to rent skis on an adjacent parcel of land. After a period of time, it stopped. And the Court

notes, "Here, in contrast," after discussing Aspen Skiing, "we have no indication that it is terminating a profitable business relationship. There is no allegation that the defendant was motivated by anything other than a desire to make more money for itself. And for all that appears in the complaint, the defendant expects to increase, not forsake, short-term profits by operating its own ski rental facility in the mid-mountain village."

So in that case there was not any evidence that there would be -- that the defendant was behaving in a way that was economically irrational or contrary to its own business interest. You can see this in all of the other cases that are cited.

The Four Corners Nephrology case, which was the other case that was cited, is also a really interesting case. In that case there was a physician who -- the Four Corners Nephrology practice, who set up a practice near Durango, but not immediately there, and the Durango medical community wanted to have a dialysis center and a nephrology practice come to Durango. The problem was there wasn't enough demand.

THE COURT: A ski area, by the way.

MS. REEVES: Yes, exactly. Which is why so many of these cases are in the Tenth Circuit, not the Third.

But, in any event, yes. So they wanted this physician to come, he was sort of the closest, to set up a

business there. But there wasn't enough business to be profitable. They negotiated back and forth with him and he refused to. So they went down -- went down elsewhere and found another practice and another hospital that was willing to send someone up to do it. Mercy Medical Center. They did so, and, as a condition of doing so, they required that they be the exclusive provider in the Durango area of these services. The disgruntled physician who was told -- who originally negotiated with the local medical community and decided not to set up his practice, sued and claimed that that exclusion that resulted from that exclusive agreement was a refusal to deal in violation of Section 2.

The Court notes very clearly that it made total sense for the -- for the Durango medical community to set up an exclusive provision and to fund the losses that the -- that the Mercy Medical Center would -- would have to eat as a result of setting up this -- setting up this practice, because that was the incentive to do so.

So in that case, again, there is a legitimate business justification for -- for denying the -- denying the plaintiff the access that he wanted.

If you go through all of the other cases --

THE COURT: Well, that was a case of market failure, it sounds like.

MS. REEVES: It was, but it was also a case, in part,

about exclusive dealing where it made a lot of sense to offer an exclusive arrangement to someone to incentivize them to do something that was pro-consumer.

THE COURT: I'm just suggesting that antitrust law should be interpreted in a way to allow -- that it did not make illegal, legitimate efforts to address in a market, market failure.

MS. REEVES: Exactly, Your Honor. The other cases from the Second Circuit are much the same.

THE COURT: This is not a market failure case.

MS. REEVES: This is most definitely not a market failure case, Your Honor.

The other cases as well from the Second Circuit are similar.

The Eatoni case, which is a Second Circuit case from 2012, the arbiter in that case, whose decision was under review on appeal, "found that the defendant, through its good-faith efforts, reached a legitimate business judgment that the parties' business model was not commercially viable."

And I could go on and on and on, Your Honor.

THE COURT: All right.

MS. REEVES: So all of those cases do not stand for the proposition that Mr. Gordon does, and to the extent they use that language, they are very much distinguishable.

One -- a second point I wanted to pause on is the

discussion that we just had of the REMS approval process. I think this is a very important point, but also somewhat confusing and complicated and technical, so I just wanted to spend a moment on it -- on it.

As the plaintiff -- or I guess in this case the defendants have alleged, the purpose of what Actelion is doing is to string us along and prevent generic entry. What the FDA has done is seen this, has set up -- and set up is even glorified, probably an overstatement. They are willing to provide these letters if and when they can in order to help the generics to respond to a problem that the FDA cannot otherwise address. The FDA does not have a formal process for approving generic companies' protocols. There are no guidance documents on how that process should work. The FDA does not collect any fees. There are not any dedicated personnel. There are no timelines. There is no set process. Instead, there is a single staffer who Ms. Walker alluded to who we've all encountered, and she's, you know, I think very frustrated because on the side, the FDA has agreed to do this.

But the suggestion that -- that this extra process that the FDA has set up in order to help the generics address the select anticompetitive conduct, that that can somehow now be turned on our heads really undermines the whole purpose of the statutory framework.

And on that note, I think on the REMS, I think it's

important, Ms. Walker alluded to this, but the purpose of the REMS is to govern post-trial premarketing, post-approval premarketing conduct. That is completely different from what we're discussing here.

And the reason we know that Congress was not concerned that generic firms would somehow seek to abuse drugs that were subject to a REMS and do horrible things with them is twofold.

The first is when it set up the REMS process, it included two provisions, one of which we've discussed and which is the brands can't use REMS to block generic entry. But the other thing it did is it explained in 21 U.S.C. 355-1(i), it explained how the REMS process would apply to generic firms. That process that's laid out in that statute, again, governs the post-approval premarketing process.

So that's sort of one side of evidence that we know, that there's not a risk that we're going to do something horrible if we're able to get these drugs other than bring products to market that will reduce costs for consumers.

The other thing we know is that Congress has set up, and the FDA in particular, a very, very heavily regulated process for bringing generic drugs to market.

It's -- in this case, the testing of our product on our end will be done under an IND. It will be tightly controlled. The patients must provide informed consent. It

will be carefully monitored by the generics, by the institutional review boards, and by the FDA. And if we aren't safe and don't follow all these rules, we are subject to FDA enforcement.

So the reason the FDA doesn't believe that this -- the concerns with the REMS should apply to sales to generic forms for drug development purposes is because there's no need for it. The REMS process is a post-approval premarketing statute, and that does apply to us in ways that are specifically designated in the statute. And then as to the drug development process, there is an extensive regulatory structure already in place.

The last and final point I just wanted to briefly touch on was Your Honor's question about whether you would be at risk of having to be involved in -- in the sort of ongoing supervision that Mr. Gordon alluded to. So, on that specific point, the answer very clearly is no. And the reason is this is not a case like Trinko where there will be an extensive ongoing business relationship going forward. In this case, we seek to purchase drugs, an unlimited number of times, in a very limited number of quantities for the purpose of doing generic drug testing. This is not going to be some constant never-ending business relationship.

As in Aspen Skiing and as in Otter Tail, there is already a market, wholesale price set for these drugs because

they already distribute them, and all we ask is that we pay whatever the fair, reasonable market wholesale price is for those and that we receive them in the limited quantities we need to bring the drugs to consumers.

The other two points that Scalia addressed I think are worth pausing on as well because they underscore why finding a refusal to deal here does not raise issues.

The first is Scalia expressed a concern that finding a refusal to deal violates Section 2 may lessen the incentive for the monopolist or the rival to both invest in economically beneficial facilities and might deter innovation. So that whole process of incentivizing brand drugs to bring drugs to market was addressed when Congress set up the Hatch-Waxman Act, and a key part of that with what we are trying to do here which is, as we sometimes call it, the grand bargain, which was to protect the ability of generic drug companies to bring drugs to market without having to go through the extensive process that they previously had to.

The other point Justice Scalia in the Trinko decision expressed his concerns about is collusion. That concern also, Your Honor, is not present here because there won't be any long-term ongoing business relationship.

THE COURT: All right. It's not in your view -- it would not be a concern of a compelled sale that this would -- it should not be the concern of this Court that a compelled

sale would unfairly skew the balance or upset the balance; rather, that it would be consistent with and maintain the balance that Congress had already struck by passing Hatch-Waxman in the first place?

MS. REEVES: Correct, Your Honor.

THE COURT: All right. Anything else?

MS. REEVES: No, Your Honor. Thank you.

THE COURT: Thank you, Ms. Reeves.

Mr. Goelman?

MR. GOELMAN: Thank you, Your Honor.

From the Court's earlier colloquy with counsel for Actelion, I think that the Court fundamentally gets it on the essential facilities doctrine, so I'm not going to belabor that argument. I just want to address one or two points.

When the Court was discussing Actelion's position that what is required is a essential facility that prevents competition in a different market, I think the Court touched on something very kind of elegant about the way that Actelion is using the essential facilities doctrine here or trying to rebut it. It is not a requirement of the essential facilities doctrine, never has been, that it be in a different market. What is required is that the essential facility itself be a bottleneck.

So if you have a bridge across the Mississippi, you can't -- and you're a railroad company, you either have to

build your own bridge or you have to use that other company's bridge to get your trains to Saint Louis.

Or, in Otter Tail, if you're a municipality and you want power, you either have to build your whole infrastructure for the delivery of that or you have to use the monopolists. That's what the bottleneck theory is.

Here there's an absolute bottleneck. Here there's a statutory bottleneck. There is no way that any of the generic companies here can possibly file an ANDA unless it gets copies of -- samples of the RLD. We tried, and this is in Apotex's complaints. We tried to get around Actelion's refusal to sell by acquiring BE samples of the Canadian version of Tracleer. We tried to use them. We tried to get the FDA to recognize that those were functionally equivalent to the American RLD, and the FDA said, no, by the statute, you have got to use these particular American versions of the RLD.

So, as opposed to all those essential facilities cases where the courts denied the essential facilities claim, where the -- the facility really wasn't essential, here it is absolutely essential.

One of the -- there's four requirements for the essential facilities. I think all cases agree on that. There's the control of the essential facility by the monopolist. And there's the inability of the competitor to reasonably or practically duplicate the facility. So it

doesn't have to be impossible.

And there's cases like JanSports that say that the facility doesn't even have to be indispensable. What it has to be is just economically infeasible.

So here, when Actelion says, well, you have other ways to complete, just bring an NDA, they're talking about a process that costs hundreds of millions of dollars. They're talking about a process that, until 1984, made sure that there was no generic competitor for the overwhelming majority of drugs.

THE COURT: Let me just ask, just so I understand exactly how this works, and the briefs were helpful on this as well as the amicus, but the whole notion of a patent is that you disclose, right? Theoretically, upon the issuance of the patent and its publication, someone skilled in the art could replicate it.

Is it your contention that the plaintiff is saying that you could create -- you could use the patent as a model, create the drug, and then go through the process of doing your own separate and independent clinical trials and market a drug based on that, that that's a viable alternative to the bioequivalency ANDA process?

MR. GOELMAN: I think that's what Actelion's --

THE COURT: Right.

MR. GOELMAN: -- position is, yes.

THE COURT: Right.

MR. GOELMAN: Correct.

THE COURT: And you're saying that's just too expensive, too long, would undermine Hatch-Waxman too clearly to represent a real alternative in the context of an essential facility analysis?

MR. GOELMAN: Exactly right. It would not allow us to reasonably or practically duplicate the facility under the -- the words of the essential facility doctrine.

THE COURT: If a generic wanted to manufacture -- wanted to develop a generic, during the term of the patent, could it reverse -- use the patent as a guide, manufacture it, and keep it inhouse, or would that violate the patent?

MR. GOELMAN: I'm sorry. Could the generic kind of take a sample and reverse engineer it?

THE COURT: Right.

MR. GOELMAN: Is that the question?

THE COURT: Well, reverse engineer it, but presumably the patent itself discloses enough of what you need to know to build it, right, make it?

MR. GOELMAN: There the Court is getting into science that I am not competent to answer.

I mean, I know that the generics in this case have developed what they think are bioequivalent drugs to Tracleer. So they already have that.

THE COURT: Right.

MR. GOELMAN: And what they want the samples for is not to create this equivalent. It's just to prove to the FDA that it actually is bioequivalent to the RLD.

THE COURT: Right. But that's -- you wouldn't have to prove that for an NDA, right? You wouldn't have to prove bioequivalency. You would just have to prove that it was safe and otherwise get approval.

MR. GOELMAN: Right, you have to prove safe and effective.

THE COURT: Right. And, just to be clear here, the allegation is that the refusal to sell frustrates the ANDA process, and because it precludes bioequivalency testing, but it doesn't preclude a new drug application based on independent development of the drug and independent testing?

MR. GOELMAN: For a different drug, you mean a different chemical entity?

THE COURT: Well, for the same drug. Can't you just make the same -- couldn't the generic -- well, my narrow question was whether or not it violated the patent for you to kind of -- assume that there was no Hatch-Waxman and that the only way to introduce a generic into the market is to make it yourself, and then in order to get through FDA regulatory approval, to go through all of the testing necessary to prove that it's safe and effective.

My question is how long -- I guess my question was a barrier to entry, how long that process would take in the absence of Hatch-Waxman. I guess the suggestion is that Hatch-Waxman proves that it -- the barrier was so high that very few ever surmounted it.

MR. GOELMAN: Right. And it would never happen because you have to -- there's so much sunk cost there, and all you would be doing is bringing to market, after the expiration of a patent, something that was already there. I mean Hatch-Waxman was --

THE COURT: You couldn't sell it effectively and competitively?

MR. GOELMAN: It would never get -- yeah, it would never get to the point where there was even a decision or a patent infringement lawsuit because nobody was developing those -- those identical chemical entities at that point. It wasn't worth it economically for companies to do that.

And that's what the -- that's the kind of flaw or one of the flaws in Actelion's patent argument is that they are presuming the validity of a patent while simultaneously ensuring that it will never be litigated because if we don't get bioequivalence samples --

THE COURT: No, I understand. I'm positing a different world where their term is expired and, you know, in a world in which Hatch-Waxman didn't exist and the patent

expired and they had no further interest or desire to sue anyone for infringement because they couldn't because the patent expired. It's angels dancing on the head of a pin but --

(Laughter.)

MR. GOELMAN: It is, but it's an interesting illustration of the problem because in that hypothetical, the patent is expired, but, for practical purposes, it may as well still be there.

THE COURT: Well, that's my point, is that -- I'm trying to assess the nature of whether -- I mean, you focused on Hatch-Waxman, but I could see some of the antitrust analysis being affected by whether or not there's an alternative to Hatch-Waxman approval of a competing drug, and it sounds like there really isn't a practical alternative.

But I appreciate you indulging my exploring. I detracted you from what you were saying.

MR. GOELMAN: I just have very little additional on the essential facilities doctrine. And the question about a case where the essential facility doctrine is actually applied, I think that we have a case, not just any old case, the case that is squarely on these facts, in this circuit, after Trinko, in the last couple years, and that's the Lannett/Celgene case, and the idea that because the Court, when it denied the motion to dismiss, didn't mention the words

"essential facilities." That we don't know why that Court actually denied the motion to dismiss I think is inaccurate. That was the only theory pled there. That was a case where Celgene raised all the same arguments that Actelion raises here.

Actelion cites in its reply brief the Plocica case where a Court says, look, this is just a five-line opinion and so I'm not going to rely on it. But in that case, the reason the Court didn't rely on that other opinion wasn't just because of the brevity of the opinion. It was because the parties hadn't cited the same precedent that the Court found it convincing.

Here, there is another District Court, and, you know, this Court may find that other District Court unpersuasive. But you can't say it's inapposite because it is this exact circumstance.

And I just wanted to return very, very briefly to the idea of what Ms. Walker calls the mother-may-I letter because the Court said, you know, how did Apotex get this letter if it's so hard to get? And the answer to that is that Apotex moved heaven and earth to get the FDA to issue this letter, and it got it in May --

THE COURT: So you're not saying it's because they have better lawyers?

(Laughter.)

MR. GOELMAN: All evidence to the contrary.

THE COURT: You resisted that. Which, by the way, I would never suggest.

(Laughter.)

MR. GOELMAN: Neither would I, Your Honor.

THE COURT: I know.

MR. GOELMAN: This letter was forthcoming in May, 2013. That was 28 months after we first asked -- Apotex first asked for the samples in this case. So even there you have years and years of monopolist profits.

You know, you see us sitting together here, counsel for the generics, and playing nice and taking turns and deferring to each other. This is not the natural state of things. These companies don't like each other. These companies compete vigorously in the market. So, you know, I hope that Apotex's negotiations with Actelion are successful and that we get, that Apotex gets the samples and Apotex gets a head start over its generic competitors, but the idea that because we have this letter, that somehow that makes it a practical solution for generics to have to go to the FDA and get these letters each and every time they want to perform bioequivalence studies on a drug with REMS would throw a huge monkey wrench in the system that Congress enacted and I --

THE COURT: Does your client know you're willing to sacrifice their interest for the good of the industry?

MR. GOELMAN: Please don't tell my client, Your Honor.

(Laughter.)

MR. GOELMAN: I just want to end by commenting on something that the Court began with. When you took the bench, you said that this is a substantial, complicated case, and that some of the briefing that you got suggested that the weight of the world was riding on this.

And I understand that parties in cases often generate these -- this parade of horribles where the sky is going to fall if their side doesn't win. In this case, Your Honor, the parade of horribles really marches. In 1984, Congress devised a system that actually works. It was a grand bargain back in days when Congress was functional and they created this industry.

If Actelion's declaratory judgment motion is granted, it would be just as effective at decimating that system as a Congressional repeal of Hatch-Waxman.

THE COURT: But the opposite of that, Mr. Goelman, is that I can't -- I shouldn't allow antitrust law to be extended so far beyond its bonds as to fix a problem that Congress didn't want to fix itself or create a remedy for. So I -- but I hear you. I understand that -- I understand that there is a system in place. And I think largely people would say it works well.

But there's -- there's limits on what I can do. I can't -- the question is what remedy does -- whether this is one of those cases in which antitrust law continues to serve an important role, or whether it's somehow in the sense of providing a viable claim, to remedy something that is anticompetitive and has all of these other potential effects. I would be worried about the tail wagging the dog, I guess. I'm not -- I'm not inclined to advance antitrust law to restrike the balance, to upset the balance, to come up with my own view of what the balance should be. But rest assured that if there's a viable claim or a properly pled claim, that I would -- equally, it would be my obligation to ensure that that proceeds through discovery if the law allows it.

MR. GOELMAN: I understand, Your Honor.

And our position is that this would not be an extension of antitrust law. It would be application of the antitrust law as it is today. And I think that the consideration of the Hatch-Waxman regulatory legislative framework isn't something that is in any way improper here.

I mean, the FDC in its brief quotes Trinko repeatedly as an antitrust analysis must always be attuned to the particular structure and circumstances of the industry at issue. And the FDC says that over and over again.

Here, Hatch-Waxman provides the framework within which the Court can apply the antitrust laws as they exist

today.

THE COURT: So, in determining whether -- how Trinko, Aspen Highlands, Otter Tail apply to this particular case, I ought to be mindful of the particular industry involved and all that goes with it, and I think this really goes to the issue which I'm going to ask Mr. Gordon about discovery, because in order to fully understand how these precedents might apply in this case, a full development of how this industry works, how this -- these particular market players acted in the context of that regulatory market, both with their distributors, with competitors, helps define those contours or make those rulings easier when all those facts are developed.

So I saw your law cited in the opposition brief, citing the Third Circuit law, the importance of the nature of the fact-specific inquiry. Certainly, the Section 1 analysis discussion on the law suggests that that's also fact-specific in the context of the rule of reason, that that's the standard to be applied in almost all cases under Section 1. So I think there's some force to that argument, and I appreciate you mentioning it here at the end.

MR. GOELMAN: Unless the Court has any other questions for me, I have nothing further.

THE COURT: All right. I think that's it.

I did want to ask Ms. Reeves if she might just give

me her point of view on how the Court should construe or apply Otter Tail, and I know you mentioned it. But, again, if you could summarize for me how you think I should view Trinko and Aspen Highlands, juxtaposed with Otter Tail in the context of the pharmaceutical industry.

MS. REEVES: Absolutely, Your Honor.

I'm actually -- just give me one moment here.

THE COURT: Take your time. I threw you a curve ball.

MR. REEVES: No, no, no.

Turn to the section of Trinko where it discusses Otter Tail because I think that's quite informative.

THE COURT: No, we're done with that, and that's not to cut you off in any way, Ms. Reeves.

I'm going to take a break, and then I'm going to provide -- since it's his motion, Mr. Gordon ought to be allowed fair rebuttal, but I'm going to need to take a break here for everyone involved.

Ms. Reeves, proceed when you're ready.

MS. REEVES: So part three of the Supreme Court's decision in Trinko is where the Court is trying to figure out what to do about the fact that the allegations in Trinko suggest what could be viewed, as the Court says, as a regulatory lapse, and that there doesn't appear to be any proof of anticompetitive animus or malice. And so when the

Court gets to this part of the opinion, it examines the two most recent refusal to deal cases, and there are others, but the two most recent ones at this point are Aspen Skiing and Trinko -- Aspen Skiing and Otter Tail.

I'm going to first discuss Aspen Skiing because I think it's very relevant to answering how you construe Otter Tail. So when the Court construes Aspen Skiing, it looks at the change in the prior course of conduct as evidence that the defendant was intending to harm competition as opposed to engaging in a legitimate -- the legitimate business, because the conduct was economically irrational. And there are lots of quotes that suggest that that's what the actual concern is.

So the Court notes that the unilateral termination of a voluntary course of dealing suggested, quote, a willingness to forsake short-term profits. Similarly, the defendant's unwillingness to renew the ticket, even if compensated at retail price, revealed a distinctly anticompetitive bent.

The Court also notes that the defendant's prior conduct in Trinko sheds no light upon the motivation of the refusal to deal and upon whether its regulatory lapses were prompted not by competitive zeal but by anticompetitive malice.

And then, finally, the Court notes that Verizon's reluctance to interconnect at the cost-based rate of compensation available under the Telecommunications Act tells

us nothing about dreams of monopoly.

So I think that context is important because what the Court then, when it turns to Otter Tail, it construes Otter Tail to support the point that in both Aspen Skiing and Otter Tail, the defendants were already engaged in providing the product to the market. So what is relevant about Aspen Skiing wasn't that there was a prior course of dealing among the parties, but that the product was already, in this case the ski lift tickets, were already being sold at a market rate and there was a price that could be paid and that the defendants in both cases, in Otter Tail and this case, chose not to wield power to potential competitors, even though that would have been profitable, because the effect of doing that was to eliminate competition over the long run. It was economically irrational for the defendant to do what it did in Otter Tail.

So in both Aspen Skiing and Otter Tail what the Court is focused on is the economic irrationality of the defendant's behavior as an indication of the anticompetitive intent.

And in this case, as Ms. Walker has already discussed, there is extensive evidence of that intent. And they're just a few points to pause on.

So, just as in Otter Tail and Aspen Skiing, we allege that Actelion already sells Tracleer and Zavesca in the marketplace. Just as in Otter Tail and Aspen Skiing, we allege that there is already a price for Tracleer and Zavesca.

Just as in Otter Tail and Aspen Skiing, we allege that Actelion has selectively chosen not to sell its products to one distinct class of customers, its potential competitors. And just as in Otter Tail and Aspen Skiing, we allege that the purpose and motivation for this behavior is to eliminate competition.

And, in closing, I think it's helpful, since you referenced Otter Tail, to note from a quote from Otter Tail. So there Otter Tail was arguing that if it had to wield power to its competitors, this, in turn, might cause its own business to go downhill. And the Supreme Court notes that the Sherman Act assumed that an enterprise will protect itself against loss of operating with superior service, lower costs and improved efficiency. Otter Tail's theory collided with the Sherman Act as it sought to substitute for competition anticompetitive uses of its dominant economic power.

THE COURT: All right.

MS. REEVES: Do you have any further questions, Your Honor?

THE COURT: Well, I guess the only -- I think I know the answer to this, but Justice Scalia was -- I guess, I don't know. Does Trinko suggest to you in any way a retreat from Otter Tail?

MS. REEVES: It does not, Your Honor. I think what -- what's going on in Trinko, Your Honor, is the

Court is concerned, and as Mr. Gordon alluded to, and I agree with him on this, there was a concern to the Court that if Section 2 is applied without limit and without -- without a consideration of whether or not businesses are doing things that could be viewed just as procompetitive as they are anticompetitive, that the plaintiffs' bar will be let forth and there will be lots of lawsuits and defendants will be chilled from engaging in things that are procompetitive.

And so in Verizon and in Trinko, the concern is that -- there was evidence that Verizon was actually filling some of the requests, just not all of them. And so, at the motion to dismiss stage, there just simply weren't enough allegations to conclude that what Verizon was doing was more likely to be anticompetitive. Indeed, consistent with Matsushita and all of the Supreme Court precedent in the antitrust context that leads up to it, the conduct could be viewed just as consistently as anticompetitive as procompetitive.

So what Scalia's concerned with in Trinko is making sure that the refusal to deal cases from Otter Tail and Aspen Skiing aren't applied in a way that will chill procompetitive behavior. And in a lot of cases, that risk might exist. The reason it doesn't exist here is to return to the context.

When Congress set up the Hatch-Waxman Act, and we referred to it as the grand bargain, but it's really important

because what it did was it provided something for everyone. So for the generics, it provided a regulatory approval pathway that meant they didn't have to do the safety and efficacy studies, and that would incentivize the first firm to get to market with 180 days of patent exclusivity which would provide them with profits and so forth, to provide them for a reason to invest in the first place.

For the brands, it provided them with patent restoration, recognizing that the whole FDA approval process can take quite a long time, and then, as a result, there could be a lessening of the time that a firm with a patent monopoly would be able to recoup the profits that incentivizes it to engage in innovation in the first place.

So Congress struck that grand bargain, as we call it, and struck that balance in order to ensure that brands would be incentivized to innovate and generic firms would be incentivized to enter the market.

So, just to return to Trinko, Justice Scalia's concern in Trinko is that there will be a reduction in the incentive to innovate. That's what's driving much of the decision, and there are quotes throughout the decision that suggest that. That reduction in the incentive to innovate is simply not present here because it's already protected by the status quo, and all they want to do is return to the status quo under which Actelion's rights as a brand are protected

through the normal ANDA application process. There's no harm to its patent right. Congress has already considered that and protected it, and all we want to do is return to the start line and return to the status quo. We're not asking Your Honor to do anything that goes beyond that.

THE COURT: All right, Ms. Reeves, thank you.

Mr. Gordon, if you don't mind, I'd like to take a short break, say 15 minutes.

MR. GORDON: Certainly, Your Honor.

THE COURT: And we'll hear you in reply, sir.

MR. GORDON: Thank you, Your Honor.

THE COURT: All right. Thank you for your patience. We'll reconvene in 15 minutes.

THE DEPUTY CLERK: All rise.

(A recess was taken at 4:04 p.m.)

THE DEPUTY CLERK: All rise.

THE COURT: All right. Thank you. Please be seated.

All right. Mr. Gordon, you've been sitting there patiently.

MR. GORDON: Thank you, Your Honor.

I'm glad to have the opportunity to speak because I'm feeling a little bit lonely on this side of the courtroom.

And I appreciate the opportunity to kind of organize my thoughts. I think that will work to everybody's benefit.

THE COURT: All right.

MR. GORDON: One thing I think I want to bring us back to, because I think it gets lost in some of the discussion, is really focusing on what the generic defendants are asking for here. What they're asking is that Actelion be forced to sell its drug to them so that they can administer it to patients. And this is a drug -- Tracleer, for example, is a black box warning. This is a drug, I don't think there's any dispute, that has some fairly serious side effects associated with it. So this is a risky drug. And if something happens, it's ours, and we're not administering it.

Now, there have been a lot of representations made about the process that they'll follow, IRBs and systems they have in place and, "We don't have to administer too much to too many people," which really kind of amounts to, "Trust us, we can handle it." And Actelion isn't -- shouldn't be required and can't, frankly, simply rely on that, that, "Trust us. We'll take -- we'll handle your drug and we'll handle it safely."

If we had never met before, Your Honor, and I came up to you on the street and I said, "Give me your car. You know what? Hey, there are traffic laws and there are police and I've got a license. I'll take care of it. Don't worry about it, and other people will be watching."

THE COURT: My son says those things to me.

(Laughter.)

THE COURT: And you know what my response is.

MR. GORDON: And what do you say? It's actually the equivalent of what they're asking for here. Right? And it plays into the policy questions that you raised.

I mean, Hatch-Waxman did strike a balance, I agree with that. Congress struck a balance. It wanted to provide certain benefits to the generics, provide them with access to the marketplace, provide certain protections for the branded companies, intellectual property protection and the like.

And the question here is now, to the extent with the REMS, with the overlay of the REMS, if that balance has been changed, if it has been altered in some way, what's the fix?

All right. The problem with antitrust is that it fixes one side of the balance. Antitrust can deal with the issue of whether or not there should be access here. What it can't deal with is the issue of Actelion's safety concerns, which are legitimate safety concerns.

This is a legislative problem. This is not a problem that should be within the purview of antitrust litigation. And you know, in both -- and I think related is also the perspective that this brings to cases like Otter Tail and Aspen Skiing.

In Otter Tail and Aspen Skiing, what was going on in both of those cases, the attempted monopolist was refusing to do things that fell within what it did -- for the plaintiffs

in those cases and for others, it fell within the realm of the type of services that they provided to others as part of their business plan.

Here, Actelion does sell drugs to others, it's true. But it supervises the distribution of those drugs. It supervises compliance with the REMS. It supervises the way those drugs are administered to patients. It is not in the business, never has been in the business, and it does not want to be in the business of supplying samples to generics so they can just say, "Trust us, we'll administer this drug safely, you don't have to worry about it."

And the safety issues are not disputed. I mean, the safety issues really fall into the category of exactly what the Second Circuit called in Elevator, on a motion to dismiss, obvious commercial interests. Actelion has an obvious and legitimate commercial interest to make sure that its liability, reputational issues, concerns, are taken into account and are dealt with, and it doesn't have an obligation and shouldn't have an obligation as matter of antitrust to do all the things it would need to do to make sure the generics are going to do that.

THE COURT: But my question -- and I agree with the majority of that. It's just, doesn't that mean that the answer should be, "We won't sell unless, you know, all these things are in place," rather than, "We just won't sell to

you"?

I mean, I accept the principle that there is this general right to refuse to sell. And I accept the principle that that's a component of the concept of free enterprise that the Sherman Act is not only designed to protect but foster. And even accounting for Justice Scalia's comment that the antitrust laws should not be used to simply -- in a way -- because some judge think it's better for competition.

But, even accepting all of that, it's one thing to say that you can use the right to refuse to sell as a shield to prevent you from unwarranted liability. It seems to me that the defendants here are alleging something more, that you're using it as a sword, that the REMS is a -- that the combination of patent exclusivity and development of a mature market with the protection of the patent, coupled with a restrictive distribution scheme -- even an exclusive distribution scheme, coupled with the refusal to sell samples, all taken together, represent a sword that was intended to maintain and perpetuate a monopoly, even beyond the patent term, and that's -- it seems it's different than just, "I have a right to say I won't sell."

Even if you accept that principle, and even if you accept the principle that there are legitimate concerns about safety and the protection of patients, that the latter could be dealt with through the regulatory process, separate and

independent of this Court, and the former must give way, if facts are alleged and proved, that the refusal to deal is simply -- is more than just, "I don't have to be compelled to sell to someone," that it's part and parcel of an overarching scheme and plan to maintain monopolistic profits, bar legitimate competitors an entry into the market as part of a violation of Section 2.

MR. GORDON: I mean, those issues are in play here, and, frankly, that's what makes this a legislative issue because there are all those moving parts to it.

THE COURT: It's a lot of moving parts.

MR. GORDON: The thing of it is, Your Honor, that -- so that would be effectively establishing a role that says because of the REMS -- look, we have a drug with a black box warning. No one wants a black box warning. Black box warning is an anathema in the pharmaceutical industry because that is a big sign on your drug saying, "This drug is really, really risky." That is not good for business. Nobody wants that. Okay? So we have that.

So, when you have that situation, that's a given, the rule that the defendants are asking for here is in that situation, then a pharmaceutical company has an obligation to sell.

THE COURT: Well, I don't know that. I mean -- you framed it, as a good lawyer would, in the context of what

they're asking for. But what they're really asking for right now is just to deny your motion for judgment on the pleadings and to dismiss their counterclaim. What they're asking for is the opportunity to -- to develop facts, supportive of the pled facts, to show that this is a violation of Section 2, and an injunction forcing a sale is just one of the remedies.

I suppose, wouldn't it be possible to simply deny that remedy and to allow a -- if a jury were to agree with them, to simply allow for the recovery of damages?

MR. GORDON: But not -- but I think our point here is, Your Honor, if there's no duty in the first place, there's no need to proceed. And none of the facts -- none of the -- discovery is not going to change any of what we're arguing here.

THE COURT: Well, let me ask you this: What -- and I think you said it, but what is the procompetitive, legitimate business reason not to sell? The collateral consequences -- the potential consequences that flow from the strictures of the REMS?

MR. GORDON: If you're going to put on the burden -- it's not just the REMS. I mean, the REMS is an indicia of the safety issues that these drugs present. This would apply whether or not there were REMS.

But if you're going to say -- if you're going to say to drug companies, look, when you have a risky drug like this,

you have an obligation to sell, which means you then have an obligation to take on the burden of satisfying yourself and doing all the things you would do to make sure that drug is being used safely, you have that obligation or take on all that burden, you're going to run smack into -- I can guarantee you, that the price that's paid for the few samples they need to do their bioequivalence studies is not going to compensate the company for doing all that work. And it's not going to compensate the company for the risk that it has to take to make sure the drug is being used safely. So you're going to run smack into the concern that I think Justice Scalia raised in Trinko about you're impinging on the value of the innovation by forcing them to sell and taking on all these burdens.

So one is I think there's a legitimate business interest in saying no because there are legitimate safety considerations.

THE COURT: Why can't you just say, I will sell if you put -- you, at your cost, your expense, put in all the protocols, the same as the clinical trial companies we hired to do the original trials put in place, and if the FDA says you can do it, and if you bear that cost, and if you satisfy us that -- and you indemnify us for any damages or harm caused by your use of the drugs, then we'll sell?

MR. GORDON: Well, as I said before, I think under

those circumstances, Actelion would be willing to sell, but I don't think they could be compelled to sell under those circumstances because I don't think they can be compelled to take on those burdens. It's like saying -- back to the simplified car example, right? So the guy, you know, I come up to you on the street and you say, "Oh, you don't trust me? Tell you what. Give me your car and you can ride along."

I'm not required to give you my car and ride along just to make sure that you're driving safely. Maybe you would be willing to do it, maybe you won't be willing to do it, but you certainly can't be forced to do it.

THE COURT: Well, that's interesting. To me, that's a question of remedies. I'm sure, I was just -- I just grabbed their answer here. I'm sure that's pled. But I don't have a motion pending for injunction directing you to disclose -- or sell samples. I have simply an opposition to your argument that -- I don't want to mischaracterize it, but that the right to refuse to sell is -- controls this case on these facts, and under no set of facts -- I don't want to reinvent the Conley standard -- under the pled facts --

MR. GORDON: Please don't, Your Honor.

THE COURT: Under the -- under the pled facts, there is nothing illegal about our conduct.

I just want to see -- to me, the -- I mean, there may be -- certainly, they do have in Count 6 injunctive relief,

but they haven't moved for it, as you expect they would.

MR. GORDON: It's -- from that perspective, it's not a remedy issue, Your Honor. It's a question of whether or not the duty exists in the first place. A question of whether or not the obligation exists in the first place is you could actually obligate it to do all these things. So it's not a remedy question. You don't get to the remedy question until you decide there is actually a duty that has been broached, and this is -- these issues in terms of whether or not Actelion has a legitimate business interest in protecting its safety and whether it can be compelled, compelled, to take the steps necessary is a question of whether or not a duty exists in the first place.

And I'll tell you something else, Your Honor. I mean, I'm not going to belabor the caselaw that Ms. Reeves went through that we put up on the screen. But if you look at those cases and you look at them carefully, there are two things that come out.

One is that, although counsel for the defense has said that Trinko doesn't require a voluntary profitable course of dealing, every Appellate Court since Trinko has disagreed with that, including the Appellate Court in the Ninth Circuit, which is the Ninth Circuit where the Helicopteros Court sat. And I also note that the Helicopteros is the case they cite.

Also, if you look at the facts and you read that case

carefully, the plaintiff in that case, the Court found that there was a question of fact as to whether or not it was a third-party beneficiary of the prior course of dealing. So it effectively -- it effectively -- there was effectively a prior course of dealing.

But despite that, the Ninth Circuit, after the Helicopteros came down, and said there must be a voluntary course of dealing, so --

THE COURT: How do you deal with Otter Tail, though? Doesn't that just completely undermine Otter Tail as precedent?

MR. GORDON: No, I don't think it undermines. I think it clarifies and perhaps it does narrow Otter Tail as precedent.

The other thing about Otter Tail and why it's not applicable here is what I said earlier, is that in Otter Tail, there the defendant was refusing to do what it was doing for others and what it did in its ordinary course of business. So it's not at all analogous to this case.

THE COURT: And why isn't that satisfied in this context by Actelion's distribution of samples to noncompetitive companies for purposes of clinical trials?

MR. GORDON: Because -- well, because I mean, frankly, Your Honor, that's actually a perfect illustration of the principles of Trinko and the discretion that Actelion has.

When Actelion does that, it makes sure that it has the opportunity to review the protocols. It makes sure it has the opportunity to satisfy itself that it's comfortable with the -- with the study. The study is in its legitimate interest. And it is entitled to make that decision. That doesn't mean because it makes this decision in certain circumstances, it has to make that decision in all circumstances. And here, there's a legitimate interest.

What they're basically asking for is, "Give us the samples and trust us." And we're not required to do that. And we're not required -- we're not required to do what we would need to do in this case to satisfy ourselves.

The other thing -- the other point I wanted to make about the case is, is that is if you look at cases like Christy and you look at cases like Four Corners Nephrology, I mean, what those cases do teach is that it's perfectly appropriate for a monopolist to decide it does not want to set up -- help a competitor set up and take away its business. That is legitimate for a monopolist to do. It's not necessarily legitimate under the narrow facts and limited circumstances of a case like Aspen Skiing.

But I think -- and I think Ms. Reeves even quoted the portion of Christy that talks about the only motive pled there was a motive to make more money. There's nothing wrong with that.

But here, there's more in play. And there are the safety issues in play.

THE COURT: All right. So -- but you're not saying it's okay to refuse to sell to achieve or maintain a monopoly?

MR. GORDON: No. But what I'm saying is that the Court and the Court since Trinko have said we have -- we have to develop a very precise test and be very careful in determining what factors are going to allow us to determine or even raise a question of fact as to whether or not there has been an intent to achieve a monopoly.

THE COURT: All right. I think that's fair. All right.

MR. GORDON: Unless you have any other questions, Your Honor, that's all I have.

THE COURT: I don't, Mr. Gordon, but thank you.

MR. GORDON: Thank you, Your Honor.

THE COURT: All right. Anyone want to be heard on the other side briefly?

MS. WALKER: Really briefly, Your Honor. I just wanted to just say a couple of the few things raised.

Actelion's argument proves too much. It's always the case that a generic gets to use the brand's drug. All BE studies use branded drugs that are obtained directly or indirectly from the brand.

And, as we've talked about today, some 40 percent of

new drugs are covered by REMS. Many, many, many REMS-covered drugs are sold to generics including many, many with black box warnings.

In any event, it doesn't matter. You cannot defend -- the Supreme Court has held that you cannot defend anticompetitive conduct by saying it's -- it's for safety reasons, it's good public policy or, you know, this is justifiably uncompetitive conduct because I'm really promoting safety here. It's been rejected again and again. Professional Society of Engineers, American Federation of Dentists. You don't get a Sherman Act exception for safety.

I mean, you know, I suppose in Aspen Skiing they could have said, well, you know, the other ski place, they rent crappy ski equipment and that's going to be unsafe because they'll come to our mountain and, you know, break their leg or something. There is just no Sherman Act exemption for safety concerns.

In any event, his other sales concession that he just made about, yes, they do sell it to other noncompeting research organizations, but they do it because they feel that their safety concerns are sort of satisfied there, well, that proves beyond a shadow of a doubt that the REMS doesn't preclude it. Okay? That -- we have been all arguing and briefing whether the REMS precludes it or not. If they say we can exercise our discretion to sell to these other research

organizations, that are not prescribers and patients and everything, et cetera, that shows that they obviously are not barred from the REMS and they can do it.

And so, just like in Society of Dentists and American Federation -- excuse me, Society of Engineers and Federation of Dentists, you cannot excuse an antitrust violation or anticompetitive conduct by saying you're doing it in the interests of safety, Your Honor.

MR. GORDON: Your Honor, if I could -- if I could just briefly respond to the Federation of Dentists case and the Society of Engineers case.

THE COURT: Yes.

MR. GORDON: Those cases stand for the proposition you can't justify collusion by saying the collusion was required for safety reasons. There is no caselaw, and, in fact, caselaw is to the contrary, that safety considerations can't be legitimate business justifications for unilateral conduct.

THE COURT: All right. Mr. Gordon, let me -- the -- not Tracleer, the other drug.

MR. GORDON: Zavesca.

THE COURT: I'm sorry?

MR. GORDON: Zavesca.

THE COURT: Zavesca?

MR. GORDON: Yes.

THE COURT: Zavesca is post patent protection.

MR. GORDON: Correct, Your Honor.

THE COURT: By several months now. It's not subject to a REMS.

MR. GORDON: It's subject to a restrictive distribution plan, Your Honor.

THE COURT: Mandated by the FDA?

MR. GORDON: It is a plan that was developed by Actelion that arose out of -- it was agreed to by Actelion based on concerns expressed by the FDA in the approval process. And it was -- it is an agreed upon restricted distribution plan that was agreed to as a condition of approval.

THE COURT: But in the context of that drug, you have, I'll assume, safety concerns --

MR. GORDON: Yes.

THE COURT: -- but not to the level of the REMS. It's hard to think of a drug that isn't subject to some safety concerns that's regulated by the FDA and regulated by prescription. It's post patent term. And if I remember right, it's 67 million in gross sales?

MR. GORDON: That's about right, Your Honor.

THE COURT: So the cost associated with -- as I described it, reverse engineering it, going through separate and independent clinical trials, would just be, it seems to

me, an enormous hurdle or barrier to entry. So if you couple that with a restrictive distribution agreement and a refusal to sell, doesn't that mean that your client would perpetuate the profits associated with a monopoly in perpetuity?

MR. GORDON: Not necessarily, Your Honor. I mean, I think -- as I've said before, I think this is an issue for -- there are the safety concerns and they're very real safety concerns.

The fact that it is a -- the FDA did require a plan for dealing with what it felt was a -- the concerns about the risk/benefit ratio, and that's what the restricted distribution plan came out of, which requires limited distribution for a special distributor, training of physician, certification of physicians on the drug. So there are very real safety concerns there.

And in terms of perpetuating a monopoly, as I've said, this is an issue, to the extent there's an issue that should be fixed here, it's an issue to be fixed by Congress, and it's an issue that can be fixed by Congress, and Congress has considered fixing it twice, and that's really where the fix has to come from. And if Congress fixes it and mandates supply of samples under the kind of conditions that Congress was considering before, then, obviously, Actelion will comply with the law and provide the samples.

THE COURT: All right. Mr. Gordon, thank you.

MR. GORDON: Thank you.

THE COURT: All right.

All right. I asked your indulgence previously. I want to ask you just for another few moments while I organize my thoughts. I'm going to rule on this from the bench. It won't be a long ruling. I'm going to supplement it with a written opinion.

If you'll bear with me for just a few moments, I know you've probably got far-flung cities to travel back to, but I'll be back out in just a few moments.

THE DEPUTY CLERK: All rise.

(A recess was taken at 4:55 p.m.)

THE DEPUTY CLERK: All rise.

THE COURT: All right. Thank you. Please be seated.

All right. I appreciate the opportunity to reflect on the arguments of counsel which I appreciate very much.

Today proves the rule which I often cite that the quality of the briefing is a good predictor of the quality of the oral argument, and I appreciate both the briefs and your comments and thoughts here today.

I've concluded -- I am going to write an opinion on this. These thoughts will not be Marbury v. Madison, I can assure you, but I want to explain some of my reasoning.

I am going to deny the motion for judgment on the pleadings and deny the motion to dismiss the counterclaims.

The plaintiff here has brought a declaratory judgment action and has moved for judgment on those pleadings and moved for dismissal of the counterclaims, as I noted.

Essentially, plaintiff has asked this Court to rule now on the scant record before me and, indeed, on the pleadings themselves that its refusal to sell samples to its generic competitors is not illegal and cannot, on the facts pled, constitute a violation of Section 2 or Section 1 of the Sherman Act. I am not prepared to so rule.

I find that the determination of whether plaintiff's refusal to deal here, sell samples, amounts to protected and lawful conduct should await full discovery, and I will allow the case to proceed that way.

When I read Trinko and Aspen Highlands, I look at those cases through the lens of -- the case now almost a hundred years old, Colgate and Otter Tail, it suggests to me that the proper application of the antitrust laws is almost always a fact-specific one and, indeed, an industry-specific one. In essence, I simply can't find that or hold that Trinko supplies the simple answer to the issue that's been presented to this Court.

The FDA is not the FCC. It's a different environment. The defendants have alleged a profit motive which did not exist in Trinko. And it's clear to me that the FDA does not have the regulatory power to compel samples and

that there is no other potential remedy to a defendant suffering anticompetitive conduct in that regulatory scheme.

I am mindful of what Justice Scalia said for, indeed, what I think was a unanimous court or close to it, that it's not the role of this Court or any Court to impose its own sense of competition or fairness or to become a super-regulatory agency. That having been said, Trinko can't repeal Section 2. It survives. It's there and it's available, if the facts allow it, to prevent the improper maintenance and extension of a monopoly through improperly motivated conduct.

Here, the plaintiffs suggest to the Court that the facts would establish that its refusal to sell samples to deal with the defendants in this case was motivated by legitimate, indeed, government-mandated safety concerns. And I accept the notion that that's a legitimate business reason -- would be, if established, and not undermined by contrary evidence, a legitimate business reason not to deal.

But the defendants here paint a very different scenario and offer to prove to the Court that the existence of safety concerns is really just a beard, if you will, to mask the true motivation, motivation that might be akin to that in Aspen Holding, and that is to extract monopolistic profits, the maintenance of monopolistic profits beyond the patent term.

If the plaintiff -- rather, if the defendants can prove that the plaintiffs are motivated not so much by safety concerns but instead motivated by the desire to use the REMS or REMS equivalent, to use exclusive distribution agreements and to use a otherwise legitimate refusal to deal together to maintain and extend a monopoly, then they may very well make out a Section 2 claim. That's a decision I need not make and do not reach here.

The question, sole question, is whether or not discovery should proceed to allow the defendants to flesh out those claims, and I will allow them to do so.

I find that those counts in the answer are -- counterclaims are sufficiently pled under the Twombly/Iqbal standard in the context of this case.

I'm going to do an opinion. I'll do my own order. You'll have to indulge me a little bit since there have been a number of legitimate important issues raised by both sides that I want to make sure I address in the opinion, so it's going to take a little while to get it out, a week or two, I suppose, but bear with me.

Judge Donio stayed discovery in this matter. Is that true, Mr. Gordon?

MR. GORDON: Yes, Your Honor.

THE COURT: All right. I'll leave it to her to decide how to proceed from here. But I know of no reason why

discovery should not begin at the pace as quickly as the parties can get together with Judge Donio and do that.

Is there anything else I need to take up at this time, Mr. Gordon?

MR. GORDON: Nothing from our end, Your Honor.

THE COURT: All right. Ms. Walker?

MS. WALKER: Nothing, Your Honor.

THE COURT: All right. Again, thank you for your thoughtful comments and patience here today. I wish you safe travels back home.

RESPONSE: Thank you, Your Honor.

THE DEPUTY CLERK: All rise.

(The proceedings concluded at 5:23 p.m.)

- - - - -